Science and Ethics

La science et l'éthique

Two speakers listed in the Symposium program are not represented in this volume. Dr. Guy Ourisson and Dr. Peter Singer did not submit manuscripts of their presentations.

Deux des intervenants listés dans le programme du colloque ne sont pas représentés dans cet ouvrage. Monsieur Guy Ourisson et Monsieur Peter Singer n'ont pas soumis de versions manuscrites de leurs allocutions.

Science and Ethics

Proceedings of a symposium held in November 2000 under the auspices of The Royal Society of Canada

La science et l'éthique

Actes d'un colloque tenu en novembre 2000 sous les auspices de la Société royale du Canada

Organized by / organisé par

Howard Alper, OC, FRSC

Edited by / sous la direction de

Patricia Demers, FRSC

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Howard Alper, OC, FRSC

Introduction

The present volume records the papers delivered at the Society's Symposium on Science and Ethics held in Ottawa on Saturday, November 18th, 2000. I would like to thank the Society's Program Committee for its contributions to this symposium as well as the personnel of the Secretariat in Ottawa (Shawna Lawson, Sandy Jackson, Sophie Buoro, Nancy Lessard and Jeanne Salo) for having taken care of all organizational matters.

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Members of the Program Committee were:
Howard Alper, FRSC (Chair)
Paul-Hubert Poirier, MSRC
M. Patricia Marchak, FRSC
Patricia P. Smart, MSRC
David M. Hayne, FRSC

Le présent volume rassemble les communications présentées lors du colloque de la Société royale du Canada sur La science et l'éthique tenu à Ottawa le 18 novembre 2000. Je voudrais remercier le Comité du

programme de la Société pour son aide. Je remercie aussi le personnel du siège social de la Société à Ottawa (Shawna Lawson, Sandy Jackson, Sophie Buoro, Nancy Lessard et Jeanne Salo) qui s'est occupé de tous les aspects logistiques du colloque.

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Le Comité du programme avait pour membres :
Howard Alper, FRSC (président)
Paul-Hubert Poirier, MSRC
M. Patricia Marchak, FRSC
Patricia P. Smart, MSRC
David M. Hayne, FRSC

Bernard M. Dickens

Bernard M. Dickens

Can Science or Ethics Compromise Each Other in Human Subject Research?

Abstract

Over the last half-century, inspiration for ethical guidance in medical and much other research involving human subjects has been based on the Nuremberg Code. This Code was adopted in 1947 by the International War Crimes Tribunal that convened in Nuremberg after the Second World War to try offences charged against military personnel and their non-military collaborators, including the Nazi doctors. In contrast to the major military leaders, who were tried by tribunals of international composition, the trial of doctors accused of undertaking inhumane medical experimentation on powerless human subjects was convened by administrators of the American sector of occupied Germany. United States' lawyers conducted the prosecution before three United States' judges, drawing their evidence of principles of ethical practice in humane medical research from the American Medical Association. Nevertheless, the Code has been universally accepted as

expressing a set of foundational ethical principles of research involving human subjects.

As the Hippocratic Oath is to medicine in general, representing the noble spirit of altruism, care and conscience, the Nuremberg Code is to modern medical research in particular. As the Oath, the Code is a product of time, place and circumstance, and the Code has been broadened and adapted to evolving needs, particularly by the World Medical Association through its Declaration of Helsinki. Adopted in 1964, the Declaration has been amended four times and is currently under further consideration. Consistent throughout the Nuremberg Code and texts of the Declaration of Helsinki, however, has been insistence that ethical research requires, as a precondition, that the research project be scientifically sound. It has been noted that "The Nuremberg Code and the Declaration of Helsinki have stated that research with human subjects must, as a general condition of ethical justifiability, conform to the canons of scientific methodology. Both insist on respect for accepted scientific principles ... and the proper scientific and medical qualifications of investigators." Against this doctrinal background, however, the questions arise of appropriate responses when scientific methodology requires behaviour that in principle is ethically unacceptable, and when ethical integrity sets limits to practices compelled by scientific rigour.

Résumé

Depuis un demi-siècle, c'est le Code de Nuremberg qui encadre l'éthique dans la recherche, médicale notamment, sur des sujets humains. Ce code fut adopté en 1947 par le Tribunal international sur les crimes de guerre qui avait été constitué à Nurenberg après la Deuxième Guerre mondiale afin de juger des militaires allemands et leurs collaborateurs civils, en particulier des médecins nazis, accusés de crimes de guerre. Or, contrairement aux principaux dirigeants militaires qui furent jugés par des tribunaux à caractère international, le procès des médecins accusés d'avoir pratiqué des expériences médicales inhumaines sur des sujets sans défense fut conduit par les administrateurs du secteur américain de l'Allemagne occupée par les puissances alliées. Les procureurs, des juristes américains, menèrent les poursuites devant trois juges, américains eux aussi, en s'inspirant des préceptes d'éthique en matière de recherche médicale adoptés par l'American Medical Association. En définitive, le Code de Nurenberg allait malgré tout être universellement reconnu comme l'expression d'un ensemble de principes d'éthique applicables à tout travail de recherche faisant intervenir des sujets humains.

Le serment d'Hippocrate est à la médecine en général ce que le Code de Nurenberg est à la recherche médicale contemporaine: un noble esprit d'altruisme, une conscience et un souci du bien-être d'autrui. Tout comme le premier, le second est le produit d'une époque, d'un lieu et de circonstances. Ainsi, le code a-t-il été progressivement élargi et adapté aux nouveaux impératifs, en particulier par l'Association médicale mondiale par le biais de sa Déclaration d'Helsinki. Adoptée en 1964, la Déclaration d'Helsinki a été amendée à quatre reprises et elle est actuellement une nouvelle fois à l'étude. Le Code de Nurenberg, tout comme les textes de la Déclaration d'Helsinki, insiste abondamment sur le fait que tout projet de recherche conduit dans le respect de l'éthique doit, préalable obligé, reposer sur des fondements scientifiques sains. On a ainsi noté que "le *Code de Nurenberg* et la *Déclaration d'Helsinki* affirment que toute recherche conduite sur des sujets humains doit, pour se justifier sur le plan de l'éthique, être conforme aux canons de la méthodologie scientifique. Tous deux insistent sur le respect des principes scientifiques communément admis ... et sur les qualifications scientifiques et médicales des enquêteurs." Par contre, sur ce fond de doctrine interviennent les problématiques de la conduite à adopter lorsque la méthodologie scientifique exige des actions en principe inacceptables sur le plan de l'éthique, et lorsque l'intégrité morale impose des limites aux pratiques qu'oblige la rigueur scientifique.

Introduction

Over the last half-century, inspiration for ethical guidance in medical and much other research involving human subjects has been based on the Nuremberg Code. This Code was adopted in 1947 by the International War Crimes Tribunal that convened in Nuremberg after the Second World War to try offences charged against military personnel and their non-military collaborators, including the Nazi doctors.[1] In contrast to the major military leaders, who were tried by tribunals of international composition, the trial of doctors accused of undertaking inhumane medical experimentation on powerless human subjects was convened by administrators of the American sector of occupied Germany. United States' lawyers conducted the prosecution before three United States' judges, drawing their evidence of principles of ethical practice in humane medical research from the American Medical Association. Nevertheless, the Code has been universally accepted as expressing a set of foundational ethical principles of research involving human subjects.

As the Hippocratic Oath is to medicine in general, representing the noble spirit of altruism, care and conscience, the Nuremberg Code is to modern medical research in particular. As with the Oath, the Code is a product of time, place and circumstance,[2] and the Code has been broadened and adapted to evolving needs, particularly by the World Medical Association through its Declaration of Helsinki. Adopted in 1964, the Declaration has been amended five times, most recently in October 2000. Consistent throughout the Nuremberg Code and texts of the Declaration of Helsinki, however, has been the insistence that ethical research requires, as a precondition, that the research project be scientifically sound. It has been noted that "The *Nuremberg Code* and the *Declaration of Helsinki* have stated that research with human subjects must, as a general condition of ethical justifiability, conform to the canons of scientific methodology. Both insist on respect for accepted scientific principles ... and the proper scientific and medical qualifications of investigators."[3] Against this doctrinal background, however, the questions arise of appropriate responses when scientific methodology requires behaviour that in principle is ethically unacceptable, and

when ethical integrity sets limits to practices compelled by scientific rigour.

Wider Contexts

The potential for conflict between good science and ethics can be demonstrated, in advance of consideration of particular dilemmas, by addressing wider dimensions of medical research at the margins of research with human subjects. The Nuremberg Code requires that "The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment." The Declaration of Helsinki as amended in 1996 similarly provided that biomedical research "should be based on adequately performed laboratory and animal experimentation ..."

The claim that scientific preparation for human studies requires prior animal experimentation can frequently be maintained, resulting, for instance, in dogs being supplied for cardiac and hypertension research and mice being bred with susceptibilities to such human disorders as cancer and diabetes. Nevertheless, the ethics of animal experimentation are questionable when relevant studies can be conducted in other ways, such as by computerised models and on animal tissues, including those of animals that are humanely killed rather than required to succumb to painful and stressful conditions. Further, research is more ethically contentious when conducted on our fellow primates[4] and animals, such as dogs, that usually serve as household pets. A belief that scientific research on human biology necessarily requires prior experimentation on animals warrants careful ethical scrutiny. The October 2000 amendment of the Declaration of Helsinki more cautiously requires that medical research involving human subjects "must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature ... and on adequate laboratory and, where appropriate, animal experimentation." However, the Declaration does not address relevant criteria of appropriateness.

Research on human embryos has long been contentious. Because human embryos have the potential to develop into human beings, they

are often regarded as possessing an intrinsic value, in contrast to commodities, which have an instrumental value related to their utility. The principle has therefore been widely adopted among ethics committees and commentators that human embryos should not be created for the purpose of use only in research projects. Research, including studies intended to result in destruction of embryos, may be undertaken only on embryos originally developed, particularly by *in vitro* fertilization (IVF), in programmes designed to address patients' infertility or other reproductive health care. Embryos that by chance prove to be surplus to pursuit of that purpose may become available for research. The MRC (now CIHR)/ NSERC/ SSHRC Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (1998) provides in Article 9.4 that "It is not ethically acceptable to create human embryos specifically for research purposes."

The effect of this ethical rule is that scientific studies cannot be undertaken that depend on the creation of embryos that possess particular pre-determined genetic properties or characteristics. However, scientific studies in genetics and stem cell research, which offer enormous opportunities for therapeutic advances, cannot be conducted adequately on "spare" embryos that by chance are left over from medically assisted reproduction. They require that embryos be deliberately created, for instance by IVF or by cloning techniques, for studies that involve their ultimate destruction. In the United Kingdom, in June 2000, the government-convened Expert Advisory Group on Therapeutic Cloning recommended approval of the creation of embryos to predetermined specifications for purposes of research not aimed at reproduction. The Expert Group observed that "... even some people in the middle ground of ethical opinion may not accept that balancing the benefits of the research against the stage of development of the embryo is an appropriate basis for deciding whether to allow this form of research. Nevertheless, the science suggested that such research was desirable."[5] The U.K. government has accepted the Expert Group's recommendations, and has proposed regulatory reform to allow the creation of human embryos specifically for research. In the USA and many European countries, the scientific demand for purpose-designed embryos for stem cell research would at present appear ethically

unacceptable. As pressure for stem cell research grows, however, in response to new perceptions of its therapeutic potentials, this ethical objection is likely in time to give way to approval of responsible controlled studies on purpose-designed embryos.

At the other end of the spectrum of human life are studies conducted on newly deceased bodies. These may focus, for instance, on the means of tissue and organ preservation where transplantation is in prospect. Management of dead bodies for cadaveric organ and tissue recovery for transplantation is itself a matter more of therapeutic treatment of intended recipients than of research on the bodies, but optimization of success in organ and tissue transplantation requires research into improved means of organ and tissue preservation and preparation while they are still within the deceased bodies from which they are to be procured. Their use in research or transplantation ethically requires consent, from either donors when alive or appropriate family members following death.

However, when no consent was given before death, organ and tissue preservation or preparation may require interventions on bodies immediately after death has been determined and before family members can be contacted and their consent requested for this research. The scientific advance of transplantation techniques requires that research be undertaken into optimal management of newly deceased bodies (sometimes described as "neomorts"), but research interventions may require consent that is unobtainable in conformity with conventional ethical guidelines. These guidelines almost invariably require that those whose consent is requested should have unhurried time for reflection and consultation. This is frequently unavailable, however, when unsuspecting family members are suddenly confronted with news of a loved one's tragic accidental death, and when immediate interventions are integral to scientific studies.

Where Science May Compromise Ethics

The principle that individuals' participation in research requires their prior informed consent, expressed in the Nuremberg Code and Declaration of Helsinki, now has strong legal support. It reflects ethical principles of justice, individual self-determination and due protection of

those who lack relevant knowledge and understanding, particularly, but not only, of the risks of participation in particular studies. In some studies, however, prospective subjects' correct knowledge about their purposes and methodologies may render the studies scientifically unreliable, invalid or impossible. In psychological research into individuals' spontaneous reactions or behaviour in the face of certain stimuli or dilemmas, for instance, there may be a tendency for subjects to cater their responses to what they believe an investigator expects or wants to receive. This has been described as the "Hawthorne effect." When asked about their charitable donations or, for instance, sexual practices, individuals may bias their responses in ways that show them to be more conscientious and responsible than they are in fact. Individuals' disposition to react in ways they believe others require or expect of them is an important lubricant in social conduct, in reducing friction and promoting civility. In research, however, this tendency may mask or distort the individual's spontaneous, unaffected reaction that an investigator is seeking to induce or uncover. Investigators may therefore find it necessary to disguise or conceal the true focus of their enquiries.

For instance, in a study to determine how customers at a supermarket checkout react to realizing that they have been given an extra two dollar coin among the change to which they are entitled, informing them in advance that they will receive it, and that their reaction will then be scrutinized, would render the study results worthless. Similarly, a study in personal hygiene or public health in which people proposing to use public washrooms are asked to consent to monitoring of whether or not they wash their hands after use would negate the spontaneity at which the study is directed. In these cases, moreover, subsequently informing individuals who had pocketed the two dollar coins or failed to wash their hands that they had been observed might appear invasive, reproachful or unethical. In the former example of providing a temptation to dishonesty, the complaint of entrapment might also be raised, although in criminal law entrapment consists of inducing people to do what they would not do but for the pressure to which they were subjected, but not in providing an opportunity for them to do what they were already disposed to do without the contrived opportunity.

The 1998 Tri-Council Policy Statement proposes limits within which research that could not practicably be conducted with subjects' informed consent may be undertaken on a basis of subjects' incomplete information, or deception. It is unacceptable to conceal or misrepresent the level of physical, psychological or other risk a study entails, or information on the basis of which it is reasonably considered that a person might decline participation. For instance, a study to improve abortion patients' psychological adjustment to different types of abortion procedures might ask participants for their comfort levels at a series of times after performance of the procedures, and include a control group of women who had given birth and were bringing up their children. Women in the control group might be willing to consent periodically to complete a questionnaire on their feelings and state of mind, but those opposed in principle to abortion, as a matter of religious conviction or conscience, might not want to participate in a study designed to improve abortion services. Accordingly, it would be necessary to inform prospective recruits to the control group of the overall purpose of the study, even though due disclosure might incline them to refuse to participate, or to overstate the satisfactions and suppress the burdens of motherhood.

When information of the true purpose of a study may acceptably be initially withheld or misrepresented, the Tri-Council Policy Statement provides that "[w]henever possible and appropriate, the subjects will be provided with additional pertinent information after participation."[6] Such debriefing is intended to explain that true information could not have been presented initially for scientific reasons, and to remove misperceptions that have arisen. An investigator may also offer or be required to offer subjects the choice to have their data withdrawn from the record of the project, in order to respect their autonomy.

Some instances of unusually invasive medical investigations in which scientific purposes were found to outweigh the usual ethical considerations have involved sham surgery. For instance, one reported study[7] concerned patients suffering from Parkinson's disease, for which existing treatments are ineffective in helping them to regain lost motor function. Patients randomly allocated to one arm of the study were to have fetal neural cells surgically implanted in their brain

tissues, in light of promising evidence that fetal cell implantation might be beneficial for them, while patients allocated to the control arm were to receive the same surgical intervention but have no implantation. The scientific rationale was the requirement that the independent assessors of treatment outcomes be unaware of whether or not individual patients had received fetal cell implantation, lest such knowledge may unconsciously influence their assessments of outcomes. Accordingly, subjects in both the treatment and control arms of the study were required to experience and show evidence of receiving implantation surgery, namely the drilling of small holes in their skulls.

Ethical objection to investigators imposing such an invasive procedure on control patients, intending that they would have no beneficial effect from it, was countered by the claim that this constituted no more than a placebo-controlled study. Placebo-controlled drug studies have long been considered the gold standard of research, and require patients to take either the test drug or a placebo. Accordingly, control subjects would accept an invasive product that was not intended to provide them with a beneficial effect. Whether placebo studies are ethical when a recognized treatment is available for a condition for which a new treatment is under investigation has been a matter of considerable controversy for some time.[8] However, the administration of a placebo is not unethical in itself, provided that patients who are study subjects knowingly and freely accept the risk of allocation to receive a placebo, and so to forgo a treatment recognized as beneficial. When there is no such treatment, as in the case of Parkinson's disease, a placebo-controlled study is easier to justify. A concern arises with this disease, however, when affected patients are mentally incapable of making their own decisions on participation in studies, but are recruited on the basis of, for instance, family members' agreement.

The Tri-Council Policy Statement recognizes a further category of cases where the need for scientific advance in medical care justifies suspension of the usual ethical requirement of informed consent. A Research Ethics Board (REB) reviewing a scientifically sound proposal "may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or his or her authorized third party"[9] under specified conditions. Research to

improve medical management of health emergencies would include studies, for instance, on the treatment administered in hospital emergency departments immediately on the admission of trauma patients suffering serious injuries. Head trauma patients may be unconscious on admission and their relatives either inaccessible or too agitated or distracted by worry to be able to absorb information about proposed scientific research.

The conditions that justify non-consensual research include that there is a serious threat to the patient that requires immediate intervention and no standard efficacious treatment exists, or the research realistically promises the subject a direct benefit in comparison with standard care. Further, when the patient regains decision-making capacity or a capable third party authorized to approve the patient's participation in research becomes available, informed consent must be requested and given to allow the patient's continued involvement as a study subject.

Where Ethics May Compromise Scientific Methodology

In contrast to the instances when the need to ensure scientific reliability of research data compels refinement or compromise of the usual ethical requirements, there are instances when scientifically valid conclusions are compromised, because pursuit of scientific validity would be unethical. In drug studies, for instance, investigators may have to predetermine criteria for suspension of studies before scientific conclusions have been reached, because the risk of further studies appears excessive and unethical to impose on research subjects.

For example, in a drug study of seriously ill patients, the existing standard drug, which achieves only limited success and produces adverse effects and discomforts, may be compared to and contrasted with a new, unproven, product that the manufacturers believe will be more successful or produce lesser adverse effects. Patients will be randomly allocated to one of two arms of the study, patients in one arm receiving the existing product and those in the other receiving the unproven product that is being tested. Physicians who monitor patients' progress will be deliberately blinded as to which arm of the study each patient is in, in order to prevent observer-bias, but an independent unblinded monitoring group will receive patients' periodic assessments

while the study progresses, and therefore know whether they have been given the existing or the unproven product.

As the study proceeds, the independent monitoring group will periodically analyse and measure patients' data against predetermined "stopping rules." These will set statistical differences between the data from each arm of the study, and if a point of difference is reached, the study will be prematurely stopped. The difference may be, for instance, that patients allocated to receiving the unproven product have experienced higher rates of mortality, adverse reactions or acute discomfort than those receiving the existing product, or that patients taking the new product have made significantly better progress towards a cure of their ailment, control of its symptoms, containment of adverse effects of medication or reduction of levels of discomfort. In the former case, the unproven product will be withdrawn and the patients receiving it will be switched to the existing product. In the latter case, patients taking the existing product would often be informed that the new product appears better, and be offered access to it instead. The manufacturer may ethically be required to make the new product available to them, even before governmental approval of the new product for general prescription has been given.

The rationale for stopping rules in research is that it is unethical to have sick patients retained on an apparently harmful new product and denied the existing product, which appears superior. It is similarly unethical to maintain them on the existing product when comparable patients receiving the new product have fared significantly better. It is a matter more of judgment than of science to determine how stopping rules should be cast. If a study ends according to a stopping rule before its biostatistically-determined endpoint has been reached, however, it may remain scientifically unknown to what, if any, extent the unproven product is in fact inferior or superior to the existing product. If the study is stopped because the new product appears superior, and the product is then licenced for prescription and goes into general use, a later study may replicate the earlier design, with patients' informed consent, and bring the study of the new and the existing products to its scientific conclusions. These may identify, for instance, longer-term adverse effects of the new product, or a sub-population of patients for whom it is

contraindicated. The initial study might have found the same scientific results had it been completed, but achieving these results had to be forgone in favour of ethical values.

Other areas on which pursuit of scientific research yields to ethical principles concern studies on peculiarly vulnerable subjects. The Nuremberg Code was inspired by the vulnerability of involuntary subjects of experimentation, and the issue of research necessarily involving, for instance, young children and mentally impaired persons remains of particular sensitivity and concern. The case for undertaking such research, namely that the medical management of such vulnerable populations cannot be advanced without their participation in research, has both scientific and ethical weight at public policy, group welfare and other macroethical levels.[10] However, research proposals may have to be addressed at a microethical level that focuses on each of the vulnerable individuals who, if included among subjects of a research study, may be exposed to risk and discomfort when it is neither intended nor expected that he or she will benefit.

For instance, as an increasing proportion of the population reaches advanced age, it seems likely that age-related disabilities will attract greater concern and study. Neurological conditions including Parkinson's and Alzheimer's disease may become increasingly subject to scientific research proposals that require such interventions on demented, dependent patients as spinal taps and lumbar punctures for the acquisition or monitoring of cerebrospinal fluid. Similarly, surgery may be proposed for the introduction among patients' brain tissues of substances such as fetal neural cells that are hoped to prove beneficial to affected patients in general. Not only family members of mentally impaired elderly persons but also members of Research Ethics Boards may find it unethical to expose such persons to painful surgical or other interventions, even when outcomes may prove slightly beneficial to them. It may be more questionable on ethical grounds to give approval when the purpose of an experimental intervention is to achieve medical advances to benefit a population of patients that the persons proposed to be subjected to the intervention are unlikely to live long enough to join.

An ethical way to initiate this type of non-beneficial scientific experimentation may be found through the use of advance medical

directives.[11] By these directives, mentally competent persons may provide consent in anticipation of their future inability to express or to formulate their preferences. The aim of advance medical directives is primarily to give or deny consent to therapeutic options, such as resuscitation in the event of cardiac or respiratory failure. Directives may also be employed, however, to consent to experimental procedures to be undertaken when patients are, for instance, unconscious or incapable of comprehension or speech. If an advance directive approving experimentation has been given when a person is competent, to take effect when the person is incompetent, this will justify initiation of the experimental procedure. The procedure must be terminated on ethical grounds, however, if at the time it is undertaken the patient resists its introduction, by gesture or word, such as by pulling out a catheter or flinching away from a needle. Individuals' earlier consent to experimentation given when they were competent cannot prevail over their subsequent refusals, even when they are incompetent, unless perhaps in a bid to preserve a patient's life or to prevent his or her enduring pain.

Scientific research on young children may also be compromised or obstructed on ethical grounds, some of which may be reinforced by the law.[12] In the case, for instance, of children suffering from bacterial meningitis, a serious inflammation of the membranes covering the brain and spinal cord, investigators may propose to vary the standard treatment on diagnosis, in order to improve the rate or speed of child patients' recovery. They may find that an advance can be achieved on scientific grounds by adding a new treatment to standard care, withholding a medication in standard use, or substituting for a standard medication another that is unproven or is routinely used for other conditions but is not proven effective for meningitis. The ethical objection to undertaking a prospective study that will randomize eligible patients into groups that will receive different treatments is that, even if conscious, the children are not competent to consent, and frantic parents whose children, whether conscious, unconscious or semiconscious, are rushed into hospital emergency departments cannot ethically be asked, before their children are treated, to read and absorb details of a research proposal and exercise reflective choice on their children's participation. Parents want attending physicians to provide

their children with emergency care according to their best clinical judgment.

Imperfect but adequate science may permit gathering of data in these cases that may indicate comparative effectiveness and safety of different forms of management. Clinicians who conscientiously consider that treatments that differ from standard care are superior, on the basis, for instance, of animal studies, an accumulation of anecdotal data or successful use of those treatments in different but comparable pathologies, may adopt them into their clinical practice, perhaps following consultation with colleagues, undertaken in each individual child's best interests. Retrospective studies will in time permit the aggregation of statistics of clinical outcomes that show the superiority, inferiority or equivalence among standard and non-standard treatments. These retrospective statistical studies are based on groupings of cases that may not be scientifically matched or equivalent, and may contain elements of clinician bias, for instance in assessing patients' suitability for different treatments, speed of recovery, rates of return to normal functioning, or causes of continuing distress or of death. Nevertheless, they may offer the best data that can be acquired, since a scientifically rigorous prospective randomized controlled trial of different treatments may not be ethically feasible.

An alternative characterization of cases of this nature, where informed, reflective consent is not ethically possible, but research to improve medical care is considered urgently necessary, is that they are analogous to emergency department trauma cases. In these cases, authorities in Canada[13] and the United States[14] allow scientifically valid studies to be undertaken without patients' or their family members' consent. This illustrates the ambivalence that is often present in resolving whether in particular cases scientific requirements may compel ethical compromise or accommodation, or ethical requirements may justify conclusions based on less than optimal scientific methodologies; that is, the validity of scientific results is reduced by ethical constraints.

Ambivalent Cases

Advances in biotechnological capacity and imagination generate an array of potentials for scientific innovations to compromise traditional ethical requirements, and for ethical values to set limits to what may be initiated for the promotion of scientific understanding. For instance, gene therapy may make cautious advances to treat or prevent genetically-conditioned pathologies or disabilities, but ethical objections have mounted against genetic manipulations designed to achieve nontherapeutic enhancement of ordinary capacities,[15] and against initiatives towards births of "designer babies."[16] As against this ethical rejection of scientific means to artificially improve human inheritance,[17] the scientific enterprise may overcome ethical apprehension over the use of a proven agent of harm. The once pariah drug Thalidomide, responsible in the 1960s for births of hundreds if not thousands of children suffering from gross limb defects, has recently been scientifically tested in ethically approved studies, leading to its adoption as the drug of choice, or as a legitimate alternative treatment, in several circumstances, such as to reduce rejection of transplanted organs. It is contraindicated, of course, for women who are pregnant, or not sterile and not practicing effective contraception.

A current unresolved dilemma concerns scientific studies on the efficacy and appropriateness of use of the relatively scarce blood plasma product commonly called intravenous immune globulin (IVIG). Supply is scarce and cannot easily be increased because manufacturers depend on voluntary blood donations. High dose IVIG is increasingly applied as a "wonder product" to treat a variety of life-and health-endangering conditions, including the treatment of neuro-muscular disorders, the "flesh eating" disease (necrotizing fasciitis), multiple sclerosis and, for instance, streptococcal toxic shock syndrome. It also appears to reduce patients' sensitivity reactions from a number of causes so as to make them eligible for life-saving kidney and heart transplantation. IVIG is governmentally approved for several uses, but can lawfully be used in physicians' clinical judgment "off label" for many more. It is estimated that this fiscal year, IVIG, alone, will represent about $115 million of the combined budget of Canada's blood operators.

A medical concern is that IVIG is extensively used "off label" for conditions for which its efficacy has not been scientifically proven, although clinicians are conscientiously convinced that it will be of life- or health-saving benefit to their patients. "Off label" uses for which IVIG has not been scientifically proven effective make supplies less available for treatment of conditions for which it has been proven effective, but testing may show that, for at least some conditions, it is as effective as clinicians who use it "off label" believe. It therefore appears necessary to undertake scientific testing of "off label" IVIG applications, so that very costly but ineffective uses can be reduced and effective uses maximized.

Scientific research would require prospective, well controlled clinical trials with sample sizes of several hundred patients. However, such studies would significantly deplete the limited supplies of IVIG available for accepted therapeutic uses, unethically prejudicing the health and survival of dependent patients. Further, a placebo controlled trial, in which an inactive agent was given to some patients in order to relate their results to those of patients who received IVIG, would prejudice placebo recipients were IVIG to prove effective, and life-saving. Accordingly, while prospective scientific testing appears ethically required, it can be undertaken only at the cost of patients for whose treatment IVIG is proven effective, or by denying it to patients whose own physicians conscientiously believe it best indicated, and perhaps the only means, to preserve their health and lives, and who may be correct in their beliefs. It is unclear whether acquisition of scientific knowledge justifies the ethical costs of obtaining it, or ethical values justify postponement of scientific research until supplies of IVIG become adequate. In October 2000 the Canadian Blood Services and Héma Québec sponsored a Consensus Conference at which an independent Consensus Panel proposed a national registry for IVIG utilization, and that use without suitable evidence of effectiveness should be part only of a scientific or evaluative process.

An ethical principle that originated in the area of environmental regulation has been expanded to regulate several other areas of potential scientific initiative. Named the "precautionary principle," it appears in the 1992 Rio Declaration on Environment and Development in the

statement that "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Its commonly applied definition now is that "When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not established scientifically."[18] This reflects the traditional medical principle Do No Harm, but goes beyond it to prohibit acts whose potential for harm is theoretical but unproven. On this basis, for instance, manipulations of human genes that will affect the genetic nature of patients' offspring are opposed, for fear that they may produce disastrous and irreparable effects for future generations and populations. Research ethics guidelines accordingly forbid the altering of germline (i.e., reproductive) cells. For instance, the Council of Europe's November 1996 Convention on Human Rights and Biomedicine provides in Article 13 that "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."[19]

In January 1997, the Council of Europe's Directorate of Legal Affairs issued an Explanatory Report on the Convention, which notes that Article 13 "does not rule out interventions for a somatic purpose which might have unwanted side-effects on the germ cell line," such as "certain treatments of cancer by radiotherapy or chemotherapy, which may affect the reproductive system of the person undergoing the treatment."[20] Accordingly, the Convention would permit accidental but not deliberate genetic changes to future children. With developments in genetic knowledge based on laboratory, animal and related research, however, a time can be anticipated when purposeful manipulation of a patient's genome or embryo to affect intended children appears scientifically appropriate. For instance, the sperm or ova of patients suffering genetically-based growth retardation might be treated, their embryos might be treated *in vitro* or their fetuses treated *in utero*, so that resulting children would enjoy normal growth and they and their children would be spared painful and restricting daily growth hormone injections. As long ago as 1982, the U.S. President's Commission for the

Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which on ethical grounds called for "especially stringent" precautions, also concluded that "To turn away from gene splicing, which may provide a means of curing hereditary diseases, would itself raise serious ethical problems."[21]

The precautionary principle promotes the ethic of protecting vulnerable environments, populations and persons against potential risks in new developments that are scientifically unproven. Many ethical concerns are scientifically unprovable, since they relate to perceived dangers to values such as nondiscrimination among human populations, equitable distribution of wealth, power and opportunities, human dignity and individual self-esteem. The precautionary principle applied to research designed to test scientific hypotheses might be overrestrictive, in denying the sorts of scientific findings that have improved human health, lives and communities. Assessments of the ethical qualities of research protocols often involve risk-to-benefit evaluations and risk reduction strategies rather than the risk elimination implicit in the precautionary principle. A middle way must be sought to allow the progress of scientific understanding through methodologies that reduce potentials for inadvertent harm; that is, there must be attention to the science of doing science. Equally, the application of ethical orientations and principles in ways that frustrate scientific advances in human societies and healthcare raise profound concerns about the ethics of doing ethics.

Conclusion

Some resolution of occasional apparent conflicts between the goals of exemplary science and scrupulous ethics may be reached where it can be recognized that the pursuit of human advantage through scientific research is itself an ethical enterprise. For improved clinical and public health care, for instance, such research is often a necessity. Accordingly, ethical values would be in conflict with themselves if prioritization of one ethical value was to obstruct advancement of ethically necessary scientific understanding. It may therefore be ethically justifiable to prioritize the pursuit of superior science over pedantic enforcement of an ethical abstraction. Science itself creates hypotheses rather

than truths, however, and many scientific hypotheses are self-critical of the extent to which they may be held. Ethical constraints on scientific methodologies may justifiably limit the extent to which a scientific hypothesis may be experimentally tested on human subjects, and set one of the limits within which a scientifically reached hypothesis may be maintained. Sound science and sound ethics need not be in tension or conflict, but can be reconciled to be mutually reinforcing.

Notes

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Marie-Hélène Parizeau

La privatisation de la recherche biomédicale au Canada : enjeux éthiques

« Les transformations de l'éthique de la recherche biomédicale au Canada : économie et post-modernité. »

Résumé

La recherche biomédicale a amorcé un tournant depuis les années 90 et une nouvelle conjoncture économique, politique et idéologique, a ouvert la voie au modèle du libéralisme économique à l'américaine des nouveaux «chercheurs-entrepreneurs» ainsi qu'à la course aux brevets sur le vivant. Les comités d'éthique de la recherche (CER) se trouvent dans la situation d'assurer la qualité scientifique et éthique de la recherche biomédicale alors que certains dérapages (conflits d'intérêt, fraude scientifique) ont été portés à l'attention du public. Face aux multiples attentes, les CER se transforment en outil de contrôle des activités de la recherche. L'analyse qui suit, conclut au rétrécissement de l'éthique de la recherche biomédicale à une conformité juridico-administrative dans l'application des règles. Cette tentation bureaucratique trouve comme seule convergence possible le primat du consentement du sujet de recherche et concrètement la conformité du formulaire de consentement. A l'opposé, certains CER sont tentés par la flexibilité de l'application des normes et tendent alors vers le relativisme moral. Dans ce contexte difficile et mouvant, on peut s'interroger sur l'oubli d'une des finalités principales et historique des CER, soit la protection des sujets de recherche. Plus largement certaines questions doivent être posées pour repenser l'éthique de la recherche et aider à clarifier le rôle des CERQuels seront l'orientation et le financement de la recherche biomédicale et par qui? Quelle sera la limite de l'aliénation des parties du corps humain et des données concernant l'identité personnelle, aux lois du marché?

Abstract

Biomedical research has reached a turning point since the 1990s, and new economic, political and ideological conditions have paved the way for the model of American-style economic liberalism of new "researcher-

entrepreneurs", as well as for the race for patents on life. Research ethics committees (RECs) find themselves responsible for ensuring the scientific and ethical quality of biomedical research while certain deviations (conflicts of interest, scientific fraud) have been brought to the attention of the public. Faced with numerous expectations, the RECs are becoming control mechanisms for research activity. The following analysis concludes that biomedical research ethics is limited to legal-administrative compliance in rule enforcement. This bureaucratic temptation to restrict ethics allows for no other focus beyond the primacy of the research subject's consent and, in concrete terms, the conformity of the consent form. On the other hand, some RECs are tempted by the flexibility in enforcing standards and therefore tend towards moral relativism. In this difficult and unstable context, we might well wonder about the disregard for one of the primary historic goals of RECs, that is, to protect research subjects. Speaking more broadly, certain questions must be asked in order to rethink research ethics and to help clarify the role of RECs. For example, what will be the general direction of biomedical research, how will it be financed, and who will be responsible for such matters? How far will we go in alienating human body parts and personal identity data to market laws?

Introduction : mise en situation.

À la réunion du comité d'éthique de la recherche de l'hôpital A., le document suivant est soumis.

La compagnie pharmaceutique internationale DPT annonce la phase III de sa nouvelle molécule X-TRUC qui est un anti-viral nouveau pour le traitement du SIDA. Trois études cliniques sont prévues et doivent démarrer dans six mois. La compagnie demande si le comité d'éthique est prêt à évaluer dans trois mois, le protocole de phase III, tant au plan scientifique qu'éthique. Il est dit qu'à cette date les études de toxicologie sur l'animal à six mois seront en cours, mais on ne disposera des résultats que neuf mois après le démarrage de l'essai de phase III.

Question 1 : La demande de la compagnie vous paraît-elle acceptable au plan éthique ?

Le médecin qui soumet la demande au comité d'éthique de la recherche explique que les gens de la compagnie ont laissé entendre que seules les équipes qui acceptent les conditions qui accélèrent le processus d'évaluation du nouveau médicament seront admissibles aux deux études cliniques suivantes. Le médecin explique qu'en ce qui le concerne, son équipe de chercheurs et d'étudiants gradués a besoin de ces études et de l'argent versé par la compagnie pour poursuivre ses travaux de recherche. La moitié de ses chercheurs et des étudiants sont à contrat renouvelable à trois mois. Cette situation dure depuis 4 ans, c'est-à-dire depuis que les gouvernements ont diminué les budgets des organismes subventionnaires.

Question 2 : Le comité d'éthique de la recherche doit-il céder à la demande du médecin, sachant les conséquences à long terme de cette attitude ?

Voici une partie des questions de l'examen d'éthique médicale, auxquelles les étudiants de 2^{e} année en médecine à l'Université Laval ont eu à répondre, à l'image exacte de ce qui s'était passé, un mois auparavant, dans le comité d'éthique de la recherche dont je suis membre. Que s'est-il passé pour qu'une des plus grosses compagnies pharmaceutiques remette ainsi en question des normes de bonnes

pratiques cliniques[1] et des règles éthiques qui ont mis plus de trente ans à s'imposer au plan international ?

1. Changement de cap de l'éthique de la recherche face à la privatisation progressive de la recherche.

Force est de constater que le paysage de la recherche biomédicale au Canada a changé au tournant des années 90. Schématiquement, ce tournant se résume par une privatisation progressive de la recherche clinique au Canada. Une conjoncture économique, politique et idéologique, bref un nouveau rapport de forces entre les compagnies internationales et l'État, a permis le désengagement financier important des gouvernements, fédéral et provinciaux, de la recherche universitaire biomédicale, ouvrant ainsi la voie au modèle du libéralisme économique à l'américaine des nouveaux « chercheurs-entrepreneurs » et de la course aux brevets sur le vivant. Ce modèle est encouragé, encore récemment,[2] par les gouvernements. Soutenu par un discours idéologique néo-libéral sur le «déficit zéro», la compétitivité, l'efficience jointe à la mondialisation, ce retrait brutal des gouvernements québécois et canadien dans le financement de la recherche biomédicale a permis aux compagnies pharmaceutiques internationales d'occuper le terrain et d'imposer leurs règles de la concurrence et du profit, sans rencontrer beaucoup d'opposition, les chercheurs étant occupés à « sauver les meubles », c'est-à-dire des équipes de recherche, des emplois et le travail de plusieurs années. Notons que les gouvernements réinjectent à nouveau de l'argent dans la recherche depuis 1999, sans remettre en cause pour autant le co-financement avec les entreprises privées et le nouveau « partenariat » faisant la promotion d'une recherche scientifique orientée vers « des résultats, des brevets et des marchés ».

Ce nouveau « partenariat » (hôpital-université-industrie), qui a été favorisé par les gouvernements canadien et québécois, a introduit des facteurs de compétition, de rentabilité et de secret qui viennent bousculer les valeurs et les traditions scientifiques[3] qui maintenaient une certaine distance entre le public et le privé, évitant ainsi de confondre les objectifs des entreprises privées avec les finalités de l'État qui lui sont propres (protection et amélioration de la santé

publique, prévention, développement de la recherche fondamentale, etc...).

L'affaire Olivieri,[4] en Ontario, publiée dans les journaux en 1998, a mis de l'avant le problème de la défense de l'intégrité scientifique d'un médecin chevronné qui voulait publier les résultats négatifs et jugés dangereux d'un médicament testé en essai clinique sur des enfants malades, alors que l'hôpital universitaire, l'université et la compagnie pharmaceutique s'y opposaient sur la base de la clause de confidentialité. Ces dernières étaient en conflit d'intérêts, car la compagnie pharmaceutique devait faire don, à la fin de l'année, de 20 millions de dollars à l'université. L'hôpital et l'université n'ont pas appuyé la démarche du Dr Olivieri alors que celle-ci défendait les valeurs de l'intégrité scientifique malgré la clause de confidentialité, dans le but de promouvoir la santé future des enfants contre un médicament toxique et la libre circulation des connaissances scientifiques. Ces deux institutions ont choisi d'appliquer à la lettre la clause de confidentialité qui les liait à la compagnie pharmaceutique. Leur intérêt premier était d'obtenir l'argent promis par la compagnie et non de défendre ici la tradition d'intégrité scientifique universitaire[5]. Ces institutions étaient donc clairement en conflits d'intérêts et d'allégeance par rapport à leurs vocations institutionnelles.

Ce cas extrême et, espérons-le, rare, montre de façon éloquente les risques de dérives en matière de conflits d'intérêts et les nouveaux risques d'une recherche trop dépendante des contrats privés pour des institutions publiques, comme l'université et l'hôpital.

D'autres exemples moins spectaculaires se rencontrent dans la pratique courante des comités d'éthique de la recherche. Ce sont autant d'entorses plus ou moins graves aux principes de l'éthique de la recherche et des bonnes pratiques cliniques, ainsi par exemple : l'inclusion systématique des enfants leucémiques dans un protocole de recherche sans alternative proposée aux parents[6], l'échange de banques de sujets ou de données nominatives entre chercheurs, la collecte d'échantillons supplémentaires de sang effectuée sans rapport avec la recherche entreprise « pour des usages ultérieurs », des pressions pour une évaluation accélérée du protocole d'essai clinique « parce que la compagnie attend », les liens plus ou moins étroits entre certains

médecins-chercheurs et les compagnies pharmaceutiques[7], le développement de comités d'éthique de la recherche interne à certaines compagnies pharmaceutiques qui emploient des 'éthiciens-juristes' comme caution morale et protection juridique[8]. Certaines pratiques discutables ont débordé le cadre des usages professionnels et des murs des hôpitaux dès 1993[9]. Il semble, à tout le moins au Québec, mais vraisemblablement ailleurs au Canada, que ces phénomènes conjugués des conflits d'intérêts et de la montée du modèle du chercheur-entrepreneur aient incité du même coup les gouvernements à réviser les lignes directrices concernant l'éthique de la recherche biomédicale, et surtout le rôle des comités d'éthique de la recherche, afin de contrôler certains dérapages nuisibles à la recherche elle-même.

2. Des normes éthiques renouvelées : la tentation bureaucratique. Le rapport Deschamps,[10] soumis au Ministre de la santé du Québec en mai 1995, se présente d'ailleurs comme une réponse administrative et juridique à ce qu'il identifie comme la perte de confiance d'une partie de la population envers les chercheurs. Ce sont les individus malades dans la population qui assument physiquement les risques de la recherche biomédicale en acceptant d'y participer ; la question de la confiance est donc essentielle pour maintenir l'esprit de solidarité et la générosité dans la participation à l'effort de recherche. Le rapport Deschamps offre une réponse instaurant des mécanismes de régulation et vise à encadrer davantage les activités de la recherche, puisque les mécanismes d'autocontrôle de la communauté des chercheurs ne semblent pas suffisants dans le nouveau contexte du partenariat avec l'entreprise privée. Revu à l'interne au Ministère, un travail de consultation dans les milieux de la recherche a donné lieu à un premier document[11] qui précise le contrôle administratif en matière d'inconduite scientifique, d'évaluation éthique et scientifique de la recherche par les comités d'éthique de la recherche (CER) et de la gestion financière de la recherche biomédicale. Cette triple finalité se retrouve, deux ans plus tard, dans le *Plan d'action ministériel* de juin 1998 qui suit la révision du litigieux article 21 du Code civil relatif à la recherche avec des personnes mineures ou majeures inaptes, effectuée quelques mois plus tôt. Il faut saisir que la reconnaissance juridique des CER au Québec s'est

effectuée de façon incidente dans l'article 21 du Code civil (datant de 1993, puis modifié en 1998). Le droit, comme cela est fréquent, est venu entériner un état de fait, déjà légitimé par des pratiques administratives consensuelles et évolutives.[12] Le *Plan d'action ministériel* vient en fait préciser le cadre de référence et les normes de fonctionnement des CER au Québec, afin de délimiter leur responsabilité. La démarche repose sur la concertation des différents acteurs (hôpitaux, universités, organismes subventionnaires et corporations professionnelles) avec, comme objectifs, la sécurité et l'intégrité des sujets de recherche ainsi que la clarification des niveaux de responsabilité. Le but est d'assurer une uniformisation dans la structure et le fonctionnement des CER (composition, suivi) avec quelques contrôles assurés par le Ministère de la santé et des services sociaux. Ces procédures administratives garantissent minimalement l'éthicité des décisions des CER et leur légitimité. Le Plan d'action ministériel renvoie le contenu de l'éthique de la recherche aux « grands cadres normatifs en vigueur sur le plan international ... et à l'Énoncé de politique des Trois Conseils » (p.10).

C'est donc ce document du gouvernement fédéral publié en 1998, et qui regroupe les trois conseils subventionnaires canadiens, qu'il convient d'analyser au plan substantiel et non plus seulement au plan des procédures.

3. Des normes éthiques renouvelées : le relativisme moral dans la flexibilité de l'application des normes.

L'Énoncé de politique des trois Conseils[13] place les CER au centre de ce dispositif de contrôle éthique et scientifique de la recherche biomédicale. Les CER constituent un maillon fort de contrôle de la qualité éthique et scientifique, voire financière — si on inclut la surveillance des conflits d'intérêts — de la recherche biomédicale. L'Énoncé de politique vient préciser leur composition, leur compétence et surtout le contenu de l'éthique de la recherche à mettre en œuvre.

Nous nous en tiendrons ici à une analyse du contenu. Il faut cependant avoir à l'esprit les divers compromis[14] qui ont permis la rédaction d'un document qui porte sur toutes les recherches effectuées avec des êtres humains (de la médecine aux sciences sociales), qui sont financées par les trois Conseils. Rappelons que tout chercheur au

Canada doit se conformer aux règles éthico-administratives des Trois-Conseils s'il veut obtenir une subvention de ces organismes (voir encadré). On notera au passage que ce document est actuellement la référence en matière d'éthique de la recherche au Canada pour tous les autres organismes subventionnaires canadiens, publics ou privés.

Essentiellement, trois remarques critiques seront développées.

3.1. Première remarque : La conformité administrative tient lieu d'éducation à l'éthique de la recherche tant pour les chercheurs que pour les membres de CER.

L'Énoncé des Trois Conseils constitue essentiellement un manuel administratif qui fournit les procédures pour un bon fonctionnement des CER. Se présentant sous forme de règles, l'Énoncé procure le cadre normatif que les CER se doivent d'appliquer. Des commentaires aux règles apparaissent régulièrement afin de préciser les zones d'ombre ou les situations d'exception. À la lecture, ces règles se présentent comme un code sans justification théorique explicite, sans contexte historique permettant de comprendre la logique qui a prévalu pour le choix de telle ou telle règle. La pauvreté de la justification des règles et l'apparence d'arbitraire de certaines normes sont révélées par l'absence de cadre éthico-philosophique explicite. En l'absence d'une éthique de la recherche véritable, c'est-à-dire construite et hiérarchisée en termes de valeurs, c'est la Charte canadienne des droits et libertés qui sert de cadre de référence juridique ultime dans ce difficile équilibre entre la norme juridique et la réflexion morale (i, 8).

3.2. Deuxième remarque : Le relativisme moral devient la nouvelle éthique de la recherche.

La première courte section intitulée « contexte du cadre éthique » donne la mesure de ce relativisme moral qui reste dans l'ordre du non-dit. D'un même souffle, est énoncé « l'impératif moral bien connu du respect de la dignité humaine » (référence à Kant) avec celui du « bien-être (référence à l'utilitarisme) et de l'intégrité de la personne (référence juridique) prépondérants en recherche avec des sujets humains » (i.5). Le kantisme[15] et l'utilitarisme sont associés sans que l'on songe à s'interroger sur la compatibilité de ces deux théories

éthiques dans une éthique de la recherche. Il s'ensuit pêle-mêle une série de principes éthiques directeurs : « le respect de la dignité humaine, le respect du consentement libre et éclairé, le respect des personnes vulnérables, le respect de la vie privée et des renseignements personnels, le respect de la justice et de l'intégration, l'équilibre des avantages et des inconvénients, la réduction des inconvénients » (i.5 ; i.6). Ces principes sont « repris des lignes directrices publiées ces dernières décennies par les Conseils », la Commission royale sur les nouvelles techniques de reproduction (1993), le *Belmont Report* (USA 1979), les *Guidelines* en sciences sociales de l'UNESCO (1994) et celles de la Norvège (1994) (i.10). Quiconque connaît ces documents peut s'étonner de les voir ainsi réunis sous une même bannière éthique, tant leur genèse et leur horizon philosophico-éthique sont différents.

La section très réduite de la mise en application de ces principes (i.9) constate « la diversité des approches philosophiques » ainsi que le problème des conflits entre les principes. La « réflexion morale » individuelle du membre du CER fait face à des valeurs formelles sans contenu a priori et sans horizon d'interprétation autre que le contexte individuel et local. La conclusion est la suivante : « utilisés au mieux, ces principes feront office d'abrégé rappelant une réflexion morale plus complexe et tenant davantage compte du contexte ». Ici s'éclaire la démarche éthique : celle-ci relève essentiellement du contexte qui va guider la décision du CER local. Le contexte constitue le critère éthique réel : on hiérarchisera les principes en fonction de l'appréciation subjective des valeurs dominantes du contexte. Comment se fera la conciliation des différents jugements moraux individuels fondés sur le contexte de chaque situation singulière ? L'Énoncé des trois Conseils pose ainsi une alternative redoutable : la rigidité bureaucratique dans l'application des règles afin de mettre des limites coûte que coûte, ou la souplesse du contexte qui autorise alors tous les rapports de forces en l'absence de consensus sur les finalités de la recherche. Le relativisme moral, où chaque situation est particulière, où tout dépend du contexte, où il n'y a pas d'horizon d'universalité, fait le lit, d'une part du nihilisme — toutes les valeurs sont égales — et d'autre part du rapport de forces — la limite est posée par la convergence des intérêts dominants ou de ceux qui ont le plus de pouvoir.

On comprendra que les CER, avec un tel cadre de référence lui-même expérimental, se retrouvent très démunis et isolés dans leur décision tant au plan pratique que théorique, de par la contrainte même du cadre éthique implicite de l'Énoncé qui les cantonne à une décision relative et limitée au contexte local. L'idéologie dominante du partenariat avec l'entreprise privée où la recherche doit être « utile socialement » peut, dès lors, s'inscrire comme le contexte « naturel » à l'aune duquel les projets de recherche seront évalués.

3.3. Troisième remarque : La seule convergence possible : le primat du consentement du sujet de recherche ou le consensus minimum sur la liberté du sujet-individu.

Confronté à la proposition de participer à un essai clinique, par exemple, il revient à l'individu seul — dans son contexte — de décider s'il veut ou non participer ou se laisser porter par cette idéologie qui associe la recherche, l'utilité sociale et le progrès économique. Les CER deviennent donc les garants de cette « liberté » individuelle, en scrutant toutes les conditions du consentement à la recherche. Le cadre philosophique se déplace ici du côté de la tradition du pragmatisme américain[16] qui focalise sur la promotion de la liberté. Ainsi se dessine le triomphe du sujet-individu, mais un sujet rationnel ou non, éduqué ou non, isolé ou en communauté, qui vit dans la société postmoderne[17]. Cette logique, rappelons-le, est éloignée de celle que l'on retrouve dans les principaux codes internationaux qui ont jalonné l'histoire de la recherche biomédicale (Code de Nuremberg (1947), Helsinki (1964)-Tokyo (1975) de l'Association médicale mondiale, *Ethical Guidelines* de WHO-CIOMS[18] (1993)). Ces textes affirment la nécessité de faire de la recherche pour le bien des patients, ainsi que de concilier le progrès scientifique et la liberté individuelle avec la protection des personnes et les Droits de l'homme[19].

Ce nouveau cadre crée une situation où les critères éthiques à partir desquels le sujet prend alors sa décision importent peu au CER, dans la mesure où il a reçu l'information la plus complète et la plus claire possible. Cependant, le CER qui, dans une recherche précise, veut poser une limite à cette liberté, pourra utiliser d'autres critères éthiques comme l'évaluation des risques. Mais cette démarche éthique

reste contextuelle au CER lui-même, qui établit son seuil de tolérance à certains risques dans le cas précis de cette recherche. Il ne s'agit pas d'une démarche universalisable puisque cette limite posée n'est que le fruit d'une conjoncture (la sensibilité ou la subjectivité des membres du CER). Un autre CER pourrait juger autrement du contexte. Le seul absolu moral consensuel se résume à la liberté de consentir du sujet de recherche.

Par ailleurs, l'Énoncé des trois Conseils consacre un chapitre de 14 pages au consentement du sujet de recherche. Les autres chapitres de l'Énoncé vont s'intéresser à des situations particulières, tels les essais cliniques, les tissus humains, la recherche en génétique et la recherche sur les embryons humains. Trois petits chapitres abordent néanmoins la vie privée et la confidentialité des données, l'intégration à la recherche (dit autrement le principe de justice), la recherche avec les peuples autochtones (le principe de respect des cultures ici réduit à la question politique des recherches avec les populations amérindiennes et inuits[20]).

Quand une éthique de la recherche se rétrécit, et ultimement se fonde sur une procédure formelle et quasi-juridique de formulaire de consentement pour le sujet, alors on peut s'interroger sur l'oubli d'une des finalités principales et historique des CER, soit la protection des sujets de recherche. Cette protection est une autre expression de la solidarité sociale, c'est-à-dire cette relation qui nous lie tous au sein de notre société humaine et qui s'exprime dans nos institutions par un idéal de justice et du bien commun.

4. L'urgence d'une éthique de la recherche

Cette analyse, qui conclut au rétrécissement de l'éthique de la recherche biomédicale à une conformité juridico-administrative sous horizon de privatisation de la recherche, se fonde également sur une enquête effectuée sur les CER au Québec, en 1998[21]. À la lumière de cette enquête, il apparaît une grande diversité dans les CER au Québec tant au plan de leur composition et de leur volume de recherche, que de leur méthode d'évaluation éthique et scientifique. Établir, comme le font les gouvernements canadiens et québécois, les CER comme maillon essentiel de la qualité scientifique et éthique de la recherche biomédicale relève, à

tout le moins pour l'instant, d'un certain irréalisme à la lumière des résultats de cette enquête.[22]

Cette enquête adressée à tous les centres hospitaliers et de soins du Québec a permis de faire une liste des CER au Québec et de constater :

- la réduction du nombre des CER suite au fusion des hôpitaux[23];
- la très grande variabilité de leur composition avec deux modèles principaux — l'un dominé par la profession médicale, l'autre plus multidisciplinaire — ;
- un mode de fonctionnement qui varie en fonction du volume de protocoles évalués :

  22 CER : moins de 15 protocoles par an = 1 à 2 protocoles à l'heure;

  9 CER : de 15 à 39 protocoles par an = 2 à 3 protocoles à l'heure;

  12 CER : de 40 (sous-comités: 40-50 protocoles) à 300 protocoles par an = 4 à 6 protocoles à l'heure ;
- pas un CER ne fonctionne de la même façon dans ses évaluations éthiques et scientifiques. Certains utilisent des sous-groupes, d'autres des évaluations par correspondance, d'autres encore multiplient les réunions plénières, etc. Par un phénomène de répartition du travail, les CER ont tenté de trouver des moyens efficaces d'évaluer un nombre important de protocoles sans diminuer a priori la qualité de l'évaluation éthique et scientifique;
- la piètre reconnaissance à l'intérieur de l'hôpital du travail des CER, dont une partie repose sur le bénévolat de membres externes, pour un travail ardu et répétitif entraînant de plus en plus de responsabilités ;
- le problème de la qualification des membres des CER. On peut s'interroger sur la nécessité d'une formation minimale, surtout si la tendance gouvernementale qui veut faire des CER le point focal de la surveillance scientifique et éthique des protocoles de recherche se maintient.

Les CER sont donc des structures jeunes, mal reconnues dans le milieu hospitalo-universitaire, qui tâtonnent encore dans leur méthode

de travail et qui doivent s'adapter à toute vitesse à la nouvelle idéologie du partenariat avec les entreprises privées. Dans ce contexte, plusieurs CER, à défaut d'une éthique de la recherche ayant un contenu substantiel et d'une conception claire de l'être humain, se rabattent sur les normes juridiques du consentement et sur les lois concernant la protection de la vie privée. Cette tentation juridico-bureaucratique décrite plus haut menace le travail d'évaluation éthique des CER. Or l'éthique de la recherche dépasse largement le plancher minimum de la loi qui d'ailleurs laisse place à 'l'esprit' des lois, donc au travail d'interprétation et à l'innovation normative dès lors que surgissent de nouvelles conjonctures.

Or, socialement, de nouvelles conjonctures sont bien en route, et l'avenir de la recherche biomédicale s'engage sur des voies bien précises comme notre analyse a tenté de le montrer. Ainsi le tout dernier document de consultation du Ministre Rochon « Pour une politique scientifique du Québec »[24] donne la priorité à certains secteurs 'porteurs' de la recherche scientifique (entre autres : les 'transferts' dans la santé, le pharmaceutique, le génomique, les biotechnologies agroalimentaires p.65-69) qui sont directement arrimés à la 'compétition' économique mondiale. La politique scientifique proposée se résume à 'une intensification de la synergie des différents acteurs de l'innovation, universités, entreprises et gouvernements' : (p.4.). On ne saurait être plus clair : compétitivité et développement économique déterminent maintenant le choix des axes scientifiques et de leur financement.

Toute une série de questions et de problèmes doit être posée maintenant à l'échelle des sociétés québécoise et canadienne, et plus largement, occidentales. J'en évoquerais deux pour conclure.

Un premier problème global concerne l'orientation et le financement de la recherche biomédicale, donc les priorités que se donne l'État dans son rapport de forces avec les grandes compagnies pharmaceutiques internationales et son arrimage avec les priorités américaines de développement scientifique. Jusqu'où les chercheurs et les institutions publiques — hôpitaux, universités, gouvernements — doivent-ils se soumettre aux lois du marché, de l'efficacité et de la compétition, au détriment des traditions et des valeurs scientifiques de

libre circulation des connaissances, d'esprit critique et de collégialité ? Bref, jusqu'où la schizophrénie, ou « ce difficile équilibre » entre

A. Mode de fonctionnement des CER au Québec

1. Le chercheur doit faire approuver par un CER tout protocole de recherche portant sur des sujets humains pour être admissible aux programmes des organismes subventionnaires fédéraux et provinciaux.
2. Le chercheur doit présenter son protocole au CER de son établissement (université ou hôpital).
3. Le CER doit faire l'évaluation éthique et scientifique des protocoles de recherche en se référant à certains critères et principes énoncés dans les déclarations internationales et l'Énoncé de politique des Trois-Conseils.
4. Le CER est un comité décisionnel qui dépend généralement du conseil d'administration de l'hôpital ou du vice-rectorat à la recherche de l'université.

B. L'évaluation scientifique et éthique des protocoles de recherche par les CER

1. Le CER (ou un autre comité désigné à cet effet) doit donner un avis sur la qualité scientifique du protocole de recherche en prenant en compte les critères suivants :
   les buts de la recherche
   les méthodes scientifiques utilisées
   l'intérêt scientifique et l'intérêt thérapeutique
   la pertinence sociale de la recherche
   la qualification des chercheurs
   les situations de fraudes scientifiques ou de conflits d'intérêts.
2. Le CER doit donner un avis sur la qualité éthique du protocole de recherche en visant la protection des sujets de recherche en s'appuyant sur certains critères et principes. Le CER devrait évaluer :
   le calcul des risques et des bénéfices acceptables pour le patient et pour l'ensemble de la population (nature des risques, incidence et gravité).
   dans la juste répartition du fardeau de la recherche (exclusion ou surexploitation d'un groupe ou d'une communauté ; vulnérabilité d'un groupe particulier – enfants, personnes âgées par exemple ; normes de recrutement et mode de compensations).
   les mesures de protection de la confidentialité et de la vie privée (modalités de conservation des données, l'utilisation ultérieure du matériel , etc)

chercheur universitaire le matin et chercheur-entrepreneur l'après-midi, va-t-il nous mener ? Les finalités et les valeurs liées à la recherche biomédicale sont à rediscuter au sein de la société[25], car la recherche a des incidences sur le système de santé et ses priorités.

Le deuxième problème concerne plus précisément l'éthique de la recherche réduite au consentement du sujet. La réflexion bioéthique américaine évacue la critique et l'analyse politique qui permettraient d'ouvrir le débat aux enjeux sociaux et de justice, dépassant ainsi cette éthique de la vie bonne qui se cantonne à la relation intersubjective entre le patient-sujet de recherche et le médecin-chercheur. Il faut poser frontalement la question de la limite de l'aliénation des parties du corps humain et des données concernant l'identité personnelle aux lois du marché, alors que tout le système repose sur la participation gratuite et souvent altruiste des sujets de recherche, qu'ils soient malades ou simplement citoyens.

Que doit penser un CER lorsqu'un chercheur-entrepreneur lui explique qu'avec le tout nouvel appareil de résonance magnétique de

Pour avoir un portrait des CER, il est plus aisé de les classer en fonction du volume de protocoles évalués par année. En effet, ce volume détermine en grande partie les modalités d'organisation et le fonctionnement des CER :

- CER mixte moins de 5 protocoles par an: **10**
- CER moins de 5 protocoles par an: **7**
- CER moins de 15 protocoles par an: **5**
- CER de 15 à 39 protocoles par an: **9**
- CER de 40 (2 à 3 sous-comités: 40-50 protocoles) à 300 protocoles par an: **12**

TOTAL: 43 CER.

Comprendre le fonctionnement réel des CER s'avère difficile, mais on peut dégager quelques points de repères, en calculant la "vitesse de croisière" des CER :

- 22 CER : moins de 15 protocoles par an = 1 à 2 protocoles à l'heure;
- 9 CER : de 15 à 39 protocoles par an = 2 à 3 protocoles à l'heure;
- 12 CER : de 40 (sous-comités: 40-50 protocoles) à 300 protocoles par an = 4 à 6 protocoles à l'heure.

l'hôpital, il va pouvoir emmagasiner sur des CD-rom toutes les images cérébrales enregistrées des sujets de recherche, et monter ainsi une banque d'images croisées avec certaines données médicales qu'il pourra, par le biais de son entreprise, rendre disponibles sur Internet à d'autres chercheurs et instituts moyennant un prix à l'achat du CD ? Va-t-il proposer que des redevances soient payées aux sujets de recherche ?

Comment un CER isolé peut-il intervenir dans la marchandisation des données scientifiques qui va contre la tradition de libre-circulation des données, et dont les conséquences à terme, d'une part sélectionnent les équipes de recherche en fonction de leur capacité de payer l'accès à l'information scientifique et d'autre part agrandit l'écart entre les pays occidentaux et les autres dans le développement scientifique ?

Que doit faire un CER, lorsque régulièrement des protocoles de très grosses compagnies pharmaceutiques incluent des prélèvements sanguins supplémentaires à des fins de « tests ultérieurs », sans qu'aucunes normes de durée de conservation, d'utilisation spécifique (va-t-on faire des recherches sur des marqueurs génétiques ?), de précision sur l'utilisation des données médicales et personnelles des sujets pendant la recherche, ne soient indiquées ?

Comment un CER isolé peut-il protéger la vie privée des sujets de recherche alors qu'il n'a pas accès aux dossiers scientifiques constitués par les compagnies pharmaceutiques et qu'il n'a aucun moyen de vérifier si celles-ci respectent leurs engagements, surtout quand les essais se font dans plusieurs pays ? Comment s'assurer que tous les sujets sont traités de la même façon en regard des normes éthiques consensuelles au plan international ?

L'éthique ne peut se passer du politique qui nomme les injustices, les exploités, les complicités et les rapports de forces. Au cœur de l'éthique de la recherche se trouvent des êtres humains souvent souffrants qui espèrent bénéficier personnellement et collectivement de thérapeutiques et de nouvelles connaissances. Au cœur de l'éthique de la recherche se construit ainsi une certaine conception de notre humanité. Y participerons-nous demain comme sujets de recherche ou comme objets de commerce ?

Épilogue :

Ce texte que je viens de vous lire m'a été initialement demandé en avril 1999 par la rédaction de la revue scientifique franco-québécoise *Médecine-Science*. En mars 2000, il était accepté par la coordonnatrice française qui avait fait faire deux évaluations externes, puis, en mai, par la rédaction québécoise qui, suite aux trois évaluations externes, demandait des changements mineurs. Le 22 août 2000, le rédacteur en chef québécois acceptait l'article avec les modifications, c'est-à-dire celui que je présente ici. Le 6 septembre, je recevais les épreuves de l'article, que je renvoyais à la rédaction à Paris à la mi-septembre. Le 6 octobre dernier, je recevais par la poste une lettre de la rédaction de la revue qui « pour une raison majeure et exceptionnelle » indiquait que mon article avait fait l'objet d'une relecture et que la rédaction ne le publierait pas :

> « le caractère inusité et surtout le ton de votre article nous ont obligé à revenir sur notre décision antérieure. Et cela, nous le croyons pour le plus grand bien de notre communauté scientifique et de la société, et aussi, du moins le pensons-nous modestement, pour votre réputation de chercheure et de bioéthicienne. »

Le respect des procédures, des bonnes pratiques professionnelles et des règles de bonne gouvernance ne m'ont pas protégée ici contre l'arbitraire du pouvoir. Ce n'est plus de la science, c'est de la politique et de l'idéologie. La liberté académique peut donc être menacée par la censure comme en témoigne cette expérience.

J'ai cherché pour conclure, un mot flamboyant ou encore un mot drôle du fondateur de cette digne Société, le Marquis de Lorne, qui avait, disait-il, « an Irish soul and my Fenian title ». Un mot comme celui de Beaumarchais 'Sans la liberté de blâmer, il n'est point d'éloge flatteur'. Hélas, le temps des lumières a cédé au temps de la mondialisation, et je nous souhaite collectivement de savoir lutter pour conserver nos institutions démocratiques. Je vous remercie donc de m'avoir accueillie dans votre honorable institution.

Notes

1. G. Bouvenot, M. Vray, « Essais cliniques. *Théorie, pratique et critique* », 3ème ed., Flammarion, 1999.
2. Voir l'éditorial du Dr Labrie alors président du FRSQ (Fonds de recherches en santé du Québec), « Faire profiter la société de nos découvertes »(*Recherche en Santé*, 2, octobre 1993, p 3), et l'éditorial de Michel Bureau, actuel président du FRSQ et Pierre Boyle, directeur général: Le FRSQ prépare son plan triennal 2001-2004', recherche en santé, 24, octobre 2000.

   Conseil de recherches médicales du Canada , « Investing in Health : Sharing the Vision ». Task Force on Health Research, mars 1994.

   Conseil de recherches médicales du Canada du 7 février 1996: «Lignes directrices pour la commercialisation de la recherche médicale». Rapport du Groupe de travail sur les conflits d'intérêts en matière de propriété intellectuelle et de commercialisation.

   Ce nouveau contexte a obligé certains établissements de soins et universités à se pencher sur les règles éthiques et déontologiques acceptables dans le cadre de ce nouveau partenariat, voir par exemple:

   « Énoncé de principe en matière d'intégrité scientifique ». Conseil de recherches médicales du Canada, 1992.

   Association canadienne des professeurs d'université, « Policy statement on fraud and other misconduct in academic research ». 1992.

   Université McGill,, « Manuel des règlements et politiques du personnel enseignant », mars 1995.

   Institut universitaire de gériatrie de Montréal, «L'énoncé sur la conduite des travaux de recherche et financement par le secteur privé», août 1998.

   Université Laval, « Règlement sur la propriété intellectuelle à l'Université Laval », 1998.
3. Report of the Royal College of Physicians , « Fraud and Misconduct in Medical Research. Causes, Investigation and Prevention ». February 1991, 18p.

   M.-H. Parizeau, (1998), « Scientific Integrity » in: *Integrity in the Public and Private Domains*, A. Montefiore, D. Vines (eds), London , Routledge, 159-167.
4. *Globe and Mail*, (Toronto), 2 novembre 1998, « Salvage group tackles Sick Kids'image disaster », M. Valpy.

5. Pour une définition exhaustive de l'intégrité scientifique, on se reportera à la référence classique dans ce domaine : National Academy of Sciences, National Academy of Engineering, Institute of Medicine, *Responsible Science, Ensuring the Integrity of the Research Process*, vol 1 et 2, 1992, National Academy Press
En voici un extrait :
"Scientific research is grounded in values such as **integrity, honesty, trust, curiosity, and respect for intellectual achievement**. The expression of these values in the diverse styles and approaches of the various scientific disciplines has contributed directly to the discovery of knowledge and thus to the achievements of the U.S. scientific research entreprise. Basic to the honor system that binds the community of scientists is truthfulness, both as a moral imperative and as a fundamental operational principle in the scientific research process.'. p. 21.
6. D. Laudie, « Consentement et traitements expérimentaux dans le cas des enfants atteints de cancer », *Laval Théologique et Philosophique*, 54 (20), juin 1998, 277-305.
7. La polémique actuelle américaine sur les conflits d'intérêt de cet ordre mérite d'être soulignée. On consultera toute une série d'articles sur cette question dans le New England Journal of Medicine, dont le dernier en date : "Disclosure of Authors' Conflicts of Interest: A Follow-Up", *The New England Journal of Medicine* — February 24, 2000 —Vol. 342, No. 8.
8. Ici se pose le problème difficile de la professionnalisation de 'l'éthicien', phénomène qui permet de garantir la qualité des services rendus par un 'professionnel de l'éthique'. Cette pratique qui vient des Etats-Unis suscite de nombreux débats tant pratique (quelle formation ?) que théorique (qu'est-ce que l'expertise éthique ?). La dérive actuelle consistant à acheter les services d'un 'éthicien' qui fournit alors la rhétorique juridico-éthique permettant de légitimer certaines pratiques questionnables. Le statut 'd'expert en éthique' a pour conséquence de déqualifier le jugement éthique commun à tous les êtres humains, reconnu depuis les débuts de la philosophie, au profit d'un jugement professionnel. Ce phénomène permet également de court-circuiter les processus de participation démocratique.
Sur ces questions, on consultera :
J. Flecher, N. Quist et A. Jonsen, (1989), *Ethics Consultation in Health Care*, Ann Arbor, Health Administration Press ;

F. Baylis (ed), (1994), *The Health Care Ethics Consultant*, Totowa, Humana Press.

9. L'affaire Fabrikant en génie et l'affaire Poisson en cancérologie (le cancérologue avait falsifié certaines données afin d'inclure plus de patientes dans le protocole et de leur rendre accessible ce nouveau médicament) ont fait la une des journaux et l'objet d'enquêtes approfondies de la part des universités et des organismes concernés.

   L'affaire Fabrikant, plus complexe, concerne une accumulation de comportements frauduleux en matière de pratiques scientifiques (appropriation de données, ordre des signatures dans les articles scientifiques) et de pressions diverses dans un contexte de précarisation de l'emploi des chercheurs et a mené, en 1992, V. Fabrikant à assassiner quatre personnes, membres du Département de génie de l'Université Concordia.

   Independent Committee of Inquiry into Academic and scientific Integrity, H.W. Arthurs, R. Blais, I. Thompson, « Integrity in scolarship. A Report to Concordia University », april 1994.

10. P. Deschamps, P. Vinay, S. Cruess, *Rapport sur l'évaluation des mécanismes de contrôle en matière de recherche clinique au Québec présenté au Ministre de la Santé et des Services Sociaux du Québec*, 1995.

11. Document de travail: *Les mécanismes de contrôle en matière de recherche clinique au Québec: Bilan de la consultation et perspectives d'intervention*, Y. Gariepy, A. Jean, C. Lamarche, P. Montambault, juin 1996.

12. Sur ce point et l'évolution historique des CER au Québec :

    Eric Gagnon, (1996), *Les comités d'éthique. La recherche médicale à l'épreuve*, Québec, Les Presses de l'Université Laval.

13. Énoncé de politique des Trois Conseils, « Éthique de la recherche avec des êtres humains». Conseil de recherches médicales du Canada, Conseil de recherches en sciences naturelles et en génie du Canada, Conseil de recherches en sciences humaines du Canada, 1998.

14. Sur l'historique et les débats autour de l'Énoncé des trois Conseils : M.-H. Parizeau, (1998), "Une éthique de la recherche avec des sujets humains est-elle encore possible?" in: *Ethique de la recherche et éthique clinique*, C. Hervé (sous la direction), *Cahiers L'éthique en mouvement*, Paris, L'Harmattan, 227-241.

15. Très brièvement, on peut définir le kantisme comme une théorie morale qui accorde à l'homme une dignité propre : les choses ont un prix, ce

sont des moyens, l'homme a une dignité, il est une fin en soi. Par la raison, explique Kant au XVIIIe siècle, l'homme peut être auteur de la loi morale qu'il appliquera par respect pour celle-ci, donc pour lui-même, puisqu'il en est l'auteur. Cette autonomie de la volonté, cette vraie liberté humaine, est le propre de la dignité humaine. La valeur morale d'une action dépend donc de règles formelles que la volonté s'impose et ne peut pas être définie par un objet ou un but (le bonheur, la sagesse, par exemple).

L'utilitarisme est une théorie morale du XIXe siècle qui énonce que le but de la morale, ce qui est bien, est la maximisation de l'utilité pour le plus grand nombre. Le calcul moral va s'attacher aux conséquences de l'action et va mesurer de façon rationnelle la somme des plaisirs par rapport à la somme des déplaisirs (évaluation des besoins, des ressources, des inconvénients, des risques). Une action morale est celle qui procure le plus de plaisirs (d'utilité) dans un calcul qui inclut les autres êtres sentants (sinon, ce serait un simple calcul égoïste).

Dans le champ de l'expérimentation humaine, l'utilitariste pourra éventuellement prendre des risques importants pour un groupe de personnes pour le bien-être d'une majorité. À l'inverse, la position kantienne sera très restrictive quand elle voudra appliquer l'impératif catégorique 'agis de telle sorte que tu traites l'humanité aussi bien dans ta personne que dans la personne de tout autre toujours en même temps comme une fin, et jamais comme un moyen'. Ainsi, lorsqu'il s'agit de risques élevés pour un groupe de patients, il faut pouvoir universaliser cette action sous la forme d'une loi morale.

16. La tradition philosophique du pragmatisme américain actuellement dominante est plurielle (James, Dewey, Peirce) mais que ses racines s'enfoncent dans la création même de la nation américaine avec comme valeur emblématique : la liberté. Voir : Gérard Deledalle, *La philosophie américaine*, 1983, Lausanne, L'Age d'Homme.
17. Sur la post-modernité, je me réfère à Jean-François Lyotard, *La condition post-moderne*, 1979, Paris, les Éditions de minuit. Dans le champ de la bioéthique, les ouvrages de T. Engelhardt fournissent une illustration de la condition morale de l'individu dans la post-modernité face à des choix de santé (T. Engelhardt, *The Foundation of Bioethics*, 1996, (2nd edition), Oxford University Press).
18. CIOMS = Council for International Organizations of Medical Sciences, WHO = World Health Organization.
19. Pour une analyse de ces textes internationaux voir :

Anne Fagot-Largeault, (1985), *L'homme bio-éthique. Pour une déontologie de la recherche sur le vivant*, Paris, Maloine.

20. Cette question est très délicate dans la mesure où la version finale de l'Énoncé des Trois Conseils s'applique aussi au secteur des recherches en sciences humaines, dont l'anthropologie. En réduisant la question du respect des cultures à la question de politique canadienne des autochtones, toutes les nuances concernant le respect des différentes cultures, et on peut penser aux diverses vagues d'immigration dans la société canadienne, sont balayées. Le document préliminaire s'attaquait avec courage au problème de la diversité culturelle et introduisait une réflexion sur le consentement familial et de groupe qui aurait pu éclairer les problèmes que nous rencontrons aujourd'hui en génétique, où le consentement individuel est inadéquat puisqu'il implique de facto des informations sur les proches et la famille élargie (arbre généalogique et secret de famille, tests génétiques et porteurs, etc.).

21. M.-H. Parizeau, « *Rapport d'enquête concernant les activités des comités d'éthique clinique et des comités d'éthique de la recherche* ». Ministère de la santé et des services sociaux du Québec, 92p. Ce rapport fait suite à une première enquête effectuée en 1989.

22. Voir : M.-H. Parizeau, " Les comités d'éthique de la recherche et la pharmaco-politique: l'exemple du Québec", *Cité. Philosophie. Politique, Histoire.* no 3, (2000), Le corps humain sous influence. La bioéthique entre pouvoir et droit. (PUF), 82-95.

    L'affaire Lessard qui met en cause tant certaines pratiques dans un protocole de recherche sur le cancer de la prostate dirigé par le Dr Labrie et le rôle de suivi du CER de l'Université Laval, montre explicitement certaines lacunes du fonctionnement du CER universitaire (procès-verbaux, secrétariat, etc). (*Le Soleil*, 13 avril 2000, 'Une vraie passoire' 'Un mémo envoyé prématurément' par M. Giguère).

23. La première enquête effectuée en 1989 indiquait qu'il existait au total 56 CER au Québec dont 41 CER et 15 CER-CEC, comités mixtes traitant à la fois la recherche et la clinique. Les nouveaux résultats en 1998 donnent les chiffres suivants: au total 43 CER dont 33 CER et 10 CER-CEC (comités mixtes).

    La nette diminution du nombre de CER est essentiellement due aux fusions d'hôpitaux qui ont eu lieu dans les grands centres urbains à Montréal, à Québec et à Sherbrooke. Étant donné le volume de la recherche dans ces centres, les CER doivent évaluer plus de 200 protocoles par année. Ce phénomène induit donc des

dysfonctionnements dans les CER. Beaucoup de stratagèmes ont été développés pour pallier au volume des protocoles dans les grands centres, mais ces trésors d'imagination demandent beaucoup d'organisation, et, il faut le dire, les exigences éthiques et scientifiques restent très variables d'un CER à l'autre.

24. Document de consultation. Vue d'ensemble. *Pour une Politique scientifique du Québec*, Ministère de la Recherche, de la Science et de la Technologie du Québec, juin 2000.
25. Un timide dialogue au Québec a été amorcé récemment par le Conseil national des cycles supérieurs et la Fédération étudiante universitaire du Québec dans leur mémoire « Du savoir au développement. Pour une politique scientifique. », 1999, adressé au ministre J. Rochon du ministère de la Recherche, de la Science et de la Technologie du Québec.

Michael McDonald

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The Governance of Health Care Research Involving Human Subjects: Reflections on Ethical Policy for Science Research

Abstract

My concern in this paper is with ethical governance for research involving humans. Such governance in essence requires giving appropriate institutional expression to the basic principles of research involving humans — namely, respect for the dignity, rights and humanity of research subjects. This in turn requires the adoption of norms and practices of good governance, in particular accountability, effectiveness and transparency. My argument will be that in Canada there are serious systemic defects in governance for research involving humans and that this should occasion major concerns on the part of all the stakeholders — research subjects, researchers, research sponsors and institutions, government and the wider community — especially those that have governance responsibilities.

The basis for my presentation is the recently published Law Commission of Canada study on this topic that I headed. My research team consisted

of investigators from law, ethics, sociology, anthropology and medicine from several Canadian universities. In Part I, I briefly review our study's main findings. In Part II, I explore the notions of governance and institutional responsibility. In Part III, I consider the culture of scientific research, and in Part IV I reflect on recent debates about Canadian policy for research involving humans.

Résumé

Je voudrais aborder, dans cette communication, la question d'une gouvernance fondée sur l'éthique pour la recherche sur des sujets humains. Pour l'essentiel, un tel mode de gouvernance exigerait de donner une expression institutionnelle appropriée aux principes fondamentaux de la recherche sur des sujets humains, en l'occurrence le respect de la dignité, des droits et du caractère humain de ces sujets. Cela appellerait ainsi l'adoption de normes et de pratiques de bonne gouvernance, et en particulier la responsabilisation, l'efficacité et la transparence. Je postulerai qu'il existe au Canada de graves lacunes systémiques dans la gouvernance de la recherche sur des sujets humains, et que ces lacunes devraient profondément interpeller toutes les parties prenantes — depuis les sujets de telles recherches jusqu'aux chercheurs en passant par les bailleurs de fonds et les instituts de recherche, les pouvoirs publics et la collectivité toute entière — et surtout celles qui ont des responsabilités en matière de gouvernance.

Mon exposé s'inspire d'une étude publiée récemment sur le sujet par la Commission canadienne du droit et que j'ai dirigée. Mon équipe de recherche était composée d'enquêteurs issus de plusieurs universités canadiennes et spécialisés dans les questions de droit, d'éthique, de sociologie et d'anthropologie. Dans la Partie I, je passe rapidement en revue les principaux constats de notre étude. Dans la Partie II, j'explore les notions de gouvernance et de responsabilité des institutions. Dans la Partie III, j'aborde la question de la culture de la recherche scientifique et, dans la Partie IV, j'évoque les débats récents au sujet d'une politique canadienne de la recherche sur des sujets humains.

Science without conscience spells
but the ruin of the soul – Rabelais[1]

When Rabelais wrote these words over 450 years ago, science was in its infancy; nonetheless, his comment remains pertinent. I will contend that how our scientific institutions are governed tells us far more about the state of the scientific 'soul' than formal statements of support for ethics codes and policy statements.

My concern is with the ethical governance for research involving humans. Such governance requires giving appropriate institutional expression to the basic principles of research involving humans – namely, respect for the dignity, rights and humanity of research subjects. This in turn requires the adoption of norms and practices of good governance, in particular accountability, effectiveness and transparency. My argument will be that in Canada there are serious systemic defects in governance for research involving humans. This should occasion major concerns on the part of all the stakeholders – research subjects, researchers, research sponsors and institutions, government and the wider community – especially those that have governance responsibilities. Among other things, this will require the development of evidence-based ethics assessment – a move with obvious parallels in health care (especially evidence-based medicine) and science generally.

I will focus on the treatment of human subjects in health research even though my remarks have considerable application to the treatment of human subjects in other areas of research.[2] The basis for my presentation is the recently published Law Commission of Canada study on *the governance of health research involving human subjects* that I headed.[3] My research team consisted of investigators from law, ethics, sociology, anthropology and medicine departments within several Canadian universities.[4]

In Part I, I briefly review our study's main findings. In Part II, I explore the notions of governance and institutional responsibility. In Part III, I consider the culture of scientific research, and in Part IV I reflect on recent debates about Canadian policy for research involving humans.

Part I: Major Findings

The focus in our study was on the ethical governance of health research involving human subjects (HRIHS). We had two research questions.

1. How is this area governed in terms of "ensuring ethical research processes?"
2. How effective are existing governance relationships?[5]

We addressed the first question through a series of papers describing the formal and informal processes in place for ensuring the ethical treatment of human subjects and the promotion of socially beneficial research. For the second, two sociologists interviewed research ethics board (REB) members at five major Canadian university sites and members of national organizations involved in the governance of HRIHS. The research team also drew on its collective experience on REBs, animal care committees, and on provincial, national and international research policy advisory groups.

Our first observation is that current Canadian governance arrangements for research involving humans are complex, convoluted and confused. In his analysis of current case law, Dickens observes that in Canada "the law applies almost inadvertently to biomedical research."[6] In her paper on the application of international, national and provincial norms in Québec, Knoppers notes "complexity and ... contradiction, if not confusion."[7] For public health research, Joly states, "no one knows who governs whom."[8] For clinical research conducted in private physicians' offices, Kinsella found an almost total lack of professional oversight with the sole exception of Alberta.[9] Our general conclusion was that "Canada's complex, decentralised, multi-sourced arrangements for governing HRIHS pose major ethical challenges in terms of consistency, transparency and accountability."[10]

This is not a good situation, especially when there are major changes in the conduct and context of research:

1. Rapid scientific and technological innovation and advances
2. Multiple disciplinary and interdisciplinary research modalities
3. Commercialization and privatization

4. Globalization and harmonization.[11]

As well, there are specifically Canadian factors that shape the governance of HRIHS.[12] This includes not only the unique arrangements in place in Québec, but also the rapidly evolving situation at the federal level with respect to governance including particularly the controversies surrounding the 1998 *Tri-Council Policy Statement on the Ethical Treatment of Research Involving Humans* (*TCPS*), the creation this year of the Canadian Institutes for Health Research (CIHR), and impending changes in Health Canada's role in regulation of clinical trials and pharmaceuticals.

In regard to the effectiveness of current governance arrangements, we found that while some members of REBs believe that our current system is effective, they could offer little evidence in support.[13] The evidence that was offered was quite unconvincing in terms of providing solid and systematic reassurance, e.g., that researchers had become better at filling out forms, that different REBs arrived at convergent judgements on similar cases, that subjects rarely complained about their treatment, or even that interviewees simply felt their REBs were effective. We also learned that while REBs spend a significant amount of time for reviewing research proposals, there is little in the way of monitoring on-going research or in the retrospective assessment of completed research. Thus, while the scientific proposals being reviewed by REBs are evidence-based, the ethics reviews REBs conduct are not evidence-based. In my view, this renders the ethics review process less credible to those whose work is being reviewed. While the REB process provides front-end scrutiny, it fails to provide quality assurance and outcomes assessment.

From our study we drew a number of major conclusions.[14]

1. The complexity of Canadian governance arrangements poses major ethical challenges. Normative arrangements and processes are fragmented, unsystematic and even "inadvertent," full of major gaps, and in general inadequate to withstand the major pressures on health research today (globalization, privatization, etc.).

2. Current policies (e.g. *TCPS* and *GCP*[15]) and processes (viz., the REB system and current provincial, national and international oversight mechanisms) suffer from what we describe as "ethical tunnel vision." Bureaucratic concerns for efficiently processing research proposals crowd out explicit ethical concerns for research subjects. REBs focus on "tweaking consent forms."[16] Thus, we conclude, "the result is that the REB approval and informed consent processes bear far more moral weight than they can possibly sustain."[17]
3. While primary ethical responsibility is placed on REBs, they lack knowledge of what happens after research proposals are approved. In regard to research subjects' attitudes, Canadian research institutions are reactive rather than pro-active. The general attitude seems to be that if no one complains then it is fair to assume that everything is all right. Our system lacks "the virtuous learning loops" that ensure quality assurance and quality improvement.[18] Moreover, we lack the fundamental research that could provide well-grounded reliable evidence-based standards for assessing the quality of outcomes.
4. The current system in Canada, and internationally, for research involving humans stresses accountability ***for*** the use of research subjects, but provides no mechanisms for accountability ***to*** those subjects.[19] Research subjects are generally passive participants in the research process. They are active only when they sign consent forms and very occasionally as complainants. This very much reinforces the all too common belief that the primary ethical responsibility of researchers is "to get the consents" from subjects.

To address these major shortcomings, we offered several suggestions for major reforms for the governance of HRIHS. We put these recommendations in term of three **i's: involvement, independence and innovation**.[20] Research subjects, institutions, sponsors, and researchers should be much more **involved** in governance. Currently, REB approval and the consent process form the core of governance for the area. Research institutions and sponsors put far more care and concern into monitoring the use of research funds than into monitoring

the treatment of human subjects in research. While we have in the public and private research sectors created a genuine culture of research, scant resources have been devoted to developing a matching **ethical** culture. In terms of **independence**, those with vested interests dominate the system of governance. REBs are desperately short of needed resources. At the national level, research involving animals is much better funded and more independent of federal research sponsors than research involving humans. For **innovation**, we see the need for experimentation with new governance arrangements and for the well-grounded research that will make research ethics review and monitoring credible and accountable.

Part II: Governance and Institutional Responsibilities

I now want to elaborate on the concept of governance used in our study.[21] As a starting point, we took the definition of governance offered by the University of Ottawa's Centre for Governance: "Governance is about guiding. It is about the processes by which human organizations, whether private, public or civic, steer themselves;" it is also the ways in which organizations interact.[22] Hence, we looked at how institutions (universities, pharmaceutical companies, health research sponsors, professional bodies, etc.) oversee or guide their own research activities and at how these institutions interact.

Some general reflections on the point or purpose of governance are in order here. People create social institutions or organizations to perform tasks and reach goals that would be difficult or impossible to do on their own. To coordinate activities and achieve organizational goals, tiers are created within organizations in terms of oversight and accountability arrangements, e.g., person A reports to person B on matter X. However, tiers are not enough (pun intended). The tiered relationships must have the right substance and be effective. That is, they must align with and forward the organization's goals. It is then a matter of ensuring that in fact the tiers work in the right way: for example, given that person A is supposed to do X in pursuit of the organizational goals Z; supervisor B's responsibility is to do Y to provide oversight appropriate for ensuring (or at least substantially raising the likelihood) that A will actually do X. Second-tier oversight should produce desired

first-tier activities. This raises the *quis custodiet* question, who guards the guardians? The organization may need further tiers: a C to ensure that B does her job overseeing A, a D to oversee C, and so on. For it cannot be taken for granted in organizational contexts that people will just "do their jobs." They may substitute their personal goals for the organization's goals. They may be lazy. They may pursue narrow intra- or inter-institutional interests at the cost of central organizational interests. They may not know the limits of their own competence or stay within their appropriate organizational roles.[23]

On this view, the number and type of tiers and accountability relations should be a function of several variables. One set of variables has to do with the skills and trustworthiness of subordinates and superiors, i.e., their competence as well as their willingness (internal motivations) to do the right thing in the right way. Behaviour is also affected "externally" by the incentives and disincentives attached to choices. As well as ensuring that people do their jobs, governance is also necessary for coordinating activities in institutions, ensuring organizational continuity, determining organizational directions, managing internal and external threats and opportunities, and the like. Suffice it to say that the potential list of reasons for governance is a long one.[24]

Our conception of governance as higher order or tiered oversight provides a straightforward account of various forms of misgovernance. For example, over-governance involves redundant second (or higher) level functions. Under-governance involves deficiencies in terms of second (or higher) level functions. When the layers function at cross-purposes or have little or no connection amongst them, there are other forms of malfunctioning. While we metaphorically talk about governance at the individual level (e.g., when we talk about individual autonomy or self-governance), the conceptual home of governance is at the collective and organizational level. Accordingly, if modern scientific enquiry in the health sciences were mainly an individual matter, an investigation of governance arrangements would be largely pointless. In that case, the central concern would be with the ethics of individual researchers. However, the sciences (and this applies with special force to biomedical, biological and genetic sciences) are highly institutionalized and organised. This includes the training and accreditation of

researchers, their employment, the validation of research, its funding, and the regulation of research.

Hence, while there is definitely a need for the promotion of an ethics of research at the individual level, it would be naïve (and perhaps even disingenuous) to take this as sufficient. We need governance processes that take full account of the pervasive forces affecting research today, particularly commercialisation, globalisation, rapid and often costly scientific advances, and increasing interdisciplinarity. It is essential to take into account the complex institutional structures and cultures that make contemporary research so productive. The growth of "big" science in genetics and pharmacology should suffice to make my point. Consider, for example, how blurred the distinctions have become between public and private sector health research and between those who regulate research and those who are regulated.

Some researchers in the natural, social and human sciences would likely claim that my emphasis on organizational and inter-organizational governance is misplaced. They would argue that in the world of research today we have created a privileged form of market-place of ideas, as advanced by John Stuart Mill in defence of liberty of thought and expression.[25] They would argue that the internal dynamics of scientific discourse and peer review are such that good research will drive out poor and even fraudulent research. Thus, it could be argued that the vigorous and unfettered pursuit of the truth is in society's best interests. I would reply that in an ideal world this may be so. But in the real world, it is essential to take into account the commercial, political, personal and institutional interests that drive research. Moreover, even if it is the case that, over the long run, truth will triumph over falsehood and society will be better off, it is imperative to ask about collateral costs. The main point is that even if there were an ideal marketplace of ideas it would not have a natural tendency to guarantee respect for the legitimate interests of research subjects. Indeed, research subjects may be in even greater peril from those motivated by detached scientific curiosity than by those whose interests are more venal. It is all too easy to identify conflicts of interest in research with the pursuit of profits and to ignore the pervasive effect of personal and institutional incentives that shape research in the public sector.

For research involving humans, should one then put one's faith in the power of informed consent? Is it true that well-informed subjects are best able to protect their own interests? Informed consent offers scant protection to those who partially or wholly (e.g., infants, the comatose, the insane) are not competent to make decisions about participation in research. Moreover, the motivations assumed by the informed consent model (that research subjects are smart consumers able to make smart judgements about their best interests) is often belied by the actual behaviour of research subjects. For example, in clinical research many individuals become research subjects primarily on the basis of trust in researchers, care-givers and their institutions.[26] In particular, I believe that research subjects place a great deal of trust in the reliability and putative oversight of research institutions and research sponsors.

The misgivings we had about the governance of health research involving humans are not based on specific instances of unethical treatment of human subjects on the part of health researchers. We could not with the methodology and resources we had draw direct conclusions about the general state of tier-one research ethics in Canada whether negative or positive. Our observations were directed at governance – tier-two oversight. With governance, it is quite possible for things to go reasonably well for a while on tier-one, but not be right on the second or higher tiers.[27] For example, a company might produce reliable products and earn a decent profit despite inadequate managerial oversight. Correspondingly, there may be good oversight along with occasional tier-one failures. Indeed, one may tolerate such a situation to avoid the problems of over-governance. But the problems we face in our research system are not primarily those of over-governance but of under-governance. For Canadian research involving humans, we have a system where oversight is far too narrow and whose effectiveness is dubious.

This takes me to one further important point about governance. Good governance involves accountability. Good governance addresses what I would describe as *the reassurance problem*: namely, reassuring the vulnerable (in this case research subjects) that they will be treated appropriately, not exploited or otherwise treated unfairly. It is my belief

that the multiple segments of the Canadian research community (researchers, research institutions, sponsors and regulators) have left the reassurance problem largely unaddressed. Through REBs and verbal commitments to various ethics policies, the research community and its regulators provide the semblance of reassurance but not its substance.

Part III: The Culture of Research

In our study, we did not limit our concerns to the formal mechanisms of governance (laws, policies, procedures, reporting relationships). We were also very much concerned with the informal social realities or cultures that permeate and shape contemporary research.[28] While there is a great deal of significant research that needs to be done on the culture of research, particularly in regard to the complex relationships that obtain between researchers and research subjects, it was apparent from the institutional commitments made by those involved in the promotion, sponsorship and production of research where the predominant emphases were laid. This was on the production of research, whether for its own sake and for other benefits such as individual and institutional prestige, access to more resources, influence in setting the direction of research, and personal and corporate profit. Beyond requirements centring on the REB mechanism, we saw little evidence of a corresponding commitment to ethical research. The institutions we surveyed did little if anything to teach the ethics of research. In Canada only a small amount of research is funded on the effects of research on subjects. Membership on REBs goes largely unrecognized and unrewarded. REBs lack resources for monitoring, internal and external education, and professional support. It is fair to say that at an institutional level the commitment to ethical research is extremely thin and even skeletal.

When we look at academic and professional bodies, we saw the same thing. The ethics of research involving humans is not a central concern. As noted above, only in one province does a College of Physicians and Surgeons provide oversight for research conducted by physicians outside university and industry facilities.[29] While the ethics of research involving humans receives some academic attention in some

quarters (e.g., medicine and bioethics), it is by no means a major topic of discussion and debate across the multiple disciplines and sub-disciplines involved in such research including, I would emphasize, the humanities and social sciences.

If one thinks about the complex way in which the direction of future research is set (involving training, certification, peer review and publication), it is, I think, fair to say that the ethical treatment of research subjects is at best a peripheral concern in most disciplines. This is in large part due to the bureaucratization of ethics in the REB approval and in the informed consent processes. In effect, research ethics has been reduced to two types of paperwork: the first is involved in securing REB approval and, the second is involved in securing signed consent forms from subjects. We have created a system in which for all practical purposes the message to new and established researchers is that once the paper is processed, ethical concerns are at an end.

As evidenced in the debates around the creation of a unified Tri-Council policy for research involving humans, substantial numbers of researchers, especially in the social sciences, see research ethics processes in very adversarial terms. In particular, the REB approval process is seen as a potential threat to academic freedom of enquiry and publication. I recall well in one of the consultations of the Tri-Council Working Group an exchange between a bioethicist who served on a medical REB and a social scientist. When the bioethicist indicated that the REB could be helpful to new researchers not only in regard to ethics but also with respect to research methodologies, the social scientist was quite incredulous at the idea of a collegial, non-adversarial relationship. For the social scientist, it was clear that the REB was at best a bureaucratic inconvenience and at worst an enemy of academic freedom.

Now what I am saying here is a broad generalization about a climate of research and institutional processes. I know that there are many conscientious researchers who take very seriously their responsibilities to research subjects. However, generally such sensitivity is not cultivated or inculcated by research institutions, sponsors, or associations of researchers.

In my view, the prevailing institutional and cultural indifference to the ethics of research is both a prudential and moral error. That is,

both prudentially and morally the research community needs the trust of research subjects and the general community. Hence, it is essential that the research community be able to demonstrate that such trust is deserved. This requires transparent, accountable and effective processes of oversight that are based on solid evidence and meet relevant moral standards.

Part IV: Canadian Policy Debates

I turn now to recent Canadian debates about policy for the ethics of research involving humans. Readers who followed those debates may well have recognized that the opening quote from Rabelais appeared on the front covers of the 1996 and 1997 versions of the proposed *Code of Ethical Conduct for Research Involving Humans.*[30] From 1995-1997, I served as a member of the Tri-Council Working Group on Ethics that authored the Code and as a member of its three-person editorial committee and ultimately as its Deputy-Chair. While the Tri-Council — the Medical Research Council of Canada (MRC), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) — accepted many parts of the *Code* and made them into policy (*TriCouncil Policy Statements on Ethical Research Involving Humans*), major recommendations generated considerable controversy and were rejected by the Councils. In addition the Councils dramatically altered the proposed rationale offered for policy.[31]

During the time in which we were conducting our study for the Law Commission, the University of Ottawa was commissioned by the Tri-Council, Health Canada, the Royal College of Physicians and Surgeons, and the National Council on Ethics in Human Research (NCEHR) "to clarify and improve the long-term organisational basis" to "manage effectively and efficiently activities related to ethics of research involving humans."[32] The Ottawa study focussed primarily on governance relations with respect to oversight of the provisions of the *Tri-Council Policy Statement (TCPS).*

While we commented critically on the Ottawa study's assumptions and recommendations (particularly with respect to their dismissal of conflict of interest concerns about the role of the Tri-Council as the

author/enforcer of the policy that governs its own research funding), I agree with their assessment that the history of the adoption of the *TCPS* raises a major governance issue.[33] They noted that while the reaction of biomedical researchers to the proposed Code of Conduct in 1996 and 1997 was "generally positive," "the reaction from the social sciences and humanities and the natural sciences and engineering was highly, perhaps even violently, negative."[34]

How can this situation of researcher distrust and disaffection be dealt with in a reasonable and fair way – one that respects the legitimate interests of both researchers and research subjects? I think that one of our key recommendations would go some distance to at least providing a reasonable basis for informed discussion of central issues. This is our recommendation for "innovation" in the form of a significant research program directed at studying the actual effects of research (including REB decisions) on research subjects. Too much of the debate about the *Code* was based on anecdotal and, in some cases, absurdly hypothetical arguments. Our research showed that there is a serious lack of systematic knowledge about the effects of particular kinds of research and forms of ethical review on research subjects. This is made worse by the lack of monitoring. With careful, well-designed research and appropriate monitoring, we should be in a much better position to design effective forms of governance that are genuinely protective of the legitimate interests of research subjects and not inappropriately restrictive with respect to research. A purely regulatory approach to governance for research involving humans does not adequately address the reassurance problem – either in terms of reassuring research subjects or researchers.

However, I do want to add a caution to these remarks. I do not want to be understood as saying that changes in governance should be held off until sufficient research is complete. I believe that our study correctly identified multiple problems with the current system of governance especially in terms of the lack of transparent and accountable governance. We explicitly rejected the Ottawa study group's conclusion that ownership of the *TCPS* should remain in the hands of the three research councils.[35] In our view it is a plain conflict of interest to have research sponsors be the legislator, judge and jury (as well as the crown attorney) for the *TCPS*.[36] Indeed, I think that this monopoly

role on the part of the Councils is a major reason for the lack of knowledge about what happens to research subjects and for the "ethical tunnel vision" remarked upon in Part I. When push comes to shove, the incentives for turning a blind eye to the fate of research subjects are much greater than for evidence-based monitoring.

In the end, it is essential to remember that there is no natural alignment between the interests of the research community and the interest of research subjects. There is no "invisible hand" – whether economic or intellectual – that ensures that effective processes for vigorously conducting research will respect the rights of research subjects. It is my firmly held conviction that governance in this area cannot be the sort of *laissez-faire* régime advocated by the most strident critics of the *Code*. There is not (as the Ottawa study advocates) an adequate replacement for arm's length governance in this area. However, arm's length governance should be based on high quality information and research. This may then be a potential area of potential agreement for all affected parties.

Conclusions

My hope is that our study will lead to a serious discussion of the adequacy of governance arrangements for Canadian research involving humans and that the discussion will be much better informed than the one that took place around the *Codes* and the *TCPS*. Even with such a discussion, there are many problems to overcome in order to create effective and ethical governance arrangements. The primary difficulty I see goes back to our first general conclusion–namely, the complexity and disjointedness of our current governance arrangements. I am very concerned that if so many parties are severally responsible (research institutions, sponsors, researchers, various levels of government, professions, etc.) no one will take real responsibility. Clearly there is a need for both leadership and concerted action. The issues we have raised are both intra-institutional and inter-institutional. I worry as well that the underlying dynamics–the drivers of contemporary research in both private and public sectors–are such that the search will be for cheap bureaucratic procedures and not for meaningful measures

grounded in research and thoughtful experimentation. The problems here are both institutional (governance arrangements) and cultural.

Finally, I return to Rabelais' words: "Science without ethics spells but the ruin of the soul." I would link these words to the final paragraph of our study of governance:

> We urge a return to the fundamental concerns that motivate health research involving human subjects–the desire for socially beneficial research and the concern for the protection of human subjects. It is our conviction that these cannot be posed as an "either-or" choice. It is a "both-and" choice. Our society needs both socially beneficial research and the protection of human subjects. Without these two together, there is the serious risk of undermining the fundamental trust relations underwriting health research – the public's trust in researchers, research institutions and sponsors and more specifically, the trust of research subjects whose continuing participation in research is essential not only to health research but also to health care. Governance is about maintaining, enhancing and, where necessary, restoring trust in transparent, accountable and effective ways. It is around this goal of trust that this study of governance for HRIHS has been oriented.[37]

Notes

1. François Rabelais, Lettre de Gargantua à Pantagruel, 1532. « Science sans conscience n'est que ruine de l'âme ».
2. I use the term "research subjects" because it is common use. However, there is a good case for linguistic reform and using the term "research participants" because of its connotations of agency (on the part of participants) and partnership with researchers in a common endeavour. See See Michael McDonald *et al*, *The Governance of Health Research Involving Human Subjects*, Law Commission of Canada, Ottawa, n.d.
3. See Michael McDonald *et al*, *The Governance of Health Research Involving Human Subjects*, Law Commission of Canada, Ottawa, n.d.

4. Co-investigators: Michael Asch (Anthropology, University Victoria), Brenda Beagan (Sociology, Dalhousie), Fern Brunger (Centre for Applied Ethics, UBC), Michael Burgess (Centre for Applied Ethics, UBC), Bernard Dickens (Law, University Toronto), Jean Joly (Institut National de Santé Publique du Québec), Douglas Kinsella (Medicine, University of Calgary), Bartha Knoppers (Faculté de droit, Université de Montréal), Thérèse Leroux (Faculté de droit, Université de Montréal), Barbara McGillivray (Medicine, UBC), Marcello Otero (Sociologie, Université de Montréal).
5. *Supra* note iii, p. 7.
6. *Ibid.* p. 93.
7. *Ibid.* p. 109.
8. *Ibid.* p. 161.
9. *Ibid.* pp. 165-169.
10. *Ibid.* p. 291.
11. *Ibid.* pp. 77-80.
12. *Ibid.* pp. 80-89.
13. This is based on data from interviews. *Ibid.* pp. 173-290.
14. *Ibid.* Section F, pp. 291-319.
15. GCP refers to *Good Clinical Practices,* which is part of the International Convention on Harmonization. ICH, International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use. 1997. "Good Clinical Practice: Consolidated Guidelines ICH Harmonised Tripartite Guideline" (Ottawa, Ontario: Minister of Health).
16. Freedman at p. 325 in Harold Y. Vanderpool, *The Ethics of Research Involving Human Subjects Facing the 21st Century* (Frederick, Maryland: University Publishing Group, Inc., 1996).
17. *Ibid.* p. 294.
18. *Ibid.* p. 299.
19. *Ibid.* pp. 302-303.
20. *Ibid.* pp. 303-319.
21. *Ibid.* pp. 23-25.
22. Centre on Governance Ottawa, *Governance of the Ethical Process for Research Involving Humans*, (Ottawa: Centre on Governance, University of Ottawa, 2000).
23. The general approach taken and several of the examples offered here are taken from Allen Buchanan, "Toward a Theory of the Ethics of Bureaucratic Organizations," *Business Ethics Quarterly* 6, no. 4 (1996).

24. *Ibid.* Buchanan provides an insightful discussion of the ethics of bureaucratic institutions. My main criticism of Buchanan is that he focuses too narrowly on the principal-agent relationship and particularly on the management of agency-risk, namely, the risk that an agent's activities will serve the agent's and not the principal's interests. Buchanan is discussed in our report on pp. 27-28.
25. Mill, John Stuart. 1962. "Liberty". In *Utilitarianism, Liberty, Representative Government*, edited by A. D. Lindsay. (London: J.M. Dent & Sons Ltd). See *supra* note iii, p. 28.
26. Kass, Nancy E., Jeremy Sugarman, Ruth Faden, and Monica Schoch-Spana. 1996. "Trust: The Fragile Foundation of Contemporary Biomedical Research." *Hastings Center Report* 26(5), p. 25-29. Kass is reporting on research conducted by the U.S. Presidential Commission on the Human Radiation Experiments. Radiation Experiments, Presidential Advisory Committee on Human. 1996. "The Human Radiation Experiments: Final Report of the President's Advisory Committee" (New York: Oxford University Press).
27. *Supra* note iii, p. 24.
28. In our report (*Ibid.*), the culture and context of research is a pervasive concern. It is specifically discussed in the sections on the process and current context of research (pp. 43-91).
29. *Ibid.* pp. 165-171.
30. The Chair of the Tri-Council Working Group, Jean Joly, found this quote.
31. Compare the Ethical Framework in the 1997 *Code of Conduct for Research Involving Humans* ttp://www.ethics.ubc.ca/code/july97/ with the *Tri-Council Policy Statement* Tri-Council. 1998. "Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans" (Ottawa: Tri-Council).
32. Ottawa, Centre on Governance. 2000. "Governance of the Ethical Process for Research Involving Humans" (Ottawa: Centre on Governance, University of Ottawa) at p. 46. The main aim of the study was to determine NCEHR's role in research ethics governance *vis à vis* its sponsors – Tri-Council, Health Canada and the Royal College.
33. See Michael McDonald *et alii*, *The Governance of Health Research Involving Human Subjects*, Law Commission of Canada, Ottawa, n.d., pp. 312-313.
34. *Supra* note xxii, at p. 14. I believe that this description of the opponents of the *Code* is over broad. Prominent feminists from the social sciences

and humanities community, for example, endorsed the *Code* in its final form, Baylis, Françoise, Jocelyn Downie, and Susan Sherwin. 1999. "Women and Health Research: From Theory, to Practice, to Policy". In *Embodying Bioethics: Recent Feminist Advances*, edited by A. Donchin and L. Purdy (Lanham: Rowman & Littlefield). While there was opposition from outspoken experimental psychologists, this by no means represented all the researchers involved in human subjects research in the natural sciences and engineering. The same is true in the social sciences and the humanities.

One may speculate as to the reasons for the different reactions to the *Code* in various research communities. I would suggest three important differences. First, biomedical researchers are highly professionalised with a collective commitment to professional standards. This is not the case in the social sciences and the humanities in which membership in professional organizations is atypical. Second, in the latter community, research is much more of an individual than a team enterprise. Third, and perhaps most importantly, far more publicity and attention has been to the ethics of research in biomedical areas than in non-biomedical areas. This is due, I believe, not to any inherent lack of virtue on the part of biomedical researchers or to the inherent riskiness of biomedical research, but to greater public interest and attentiveness to health care than to other areas of research.

35. *Supra* note xxii, at p. 43.
36. *Supra* note iii, pp. 310-312.
37. *Ibid.* p. 320.

Michael Geist

Michael Geist

Old Copyright Law and New Technologies: Canadian Copyright Reform in the Digital Age

Abstract

The digital age is challenging the relevance of copyright law as never before. Each month seems to bring a new wave of Internet business models or technologies that leave many wondering whether John Barlow Perry was correct when he proclaimed in 1994 that copyright was dead. Courts are facing seminal cases that will serve as the basis for the law for years to come, while regulators are contemplating important new legislative reforms that could alter the traditional balance between the interests of creators and users.

The paper begins with consideration of the impact of present and future Internet technologies on the current copyright law. It then examines recent copyright reforms at the international level with particular emphasis on initiatives in the U.S. and European Union. In light of this examination, the Canadian copyright law framework is assessed with reviews of recent cases and policies such as Tariff 22, the private copying exemption, and the

iCraveTV Webcasting retransmission case. The paper concludes with recommendations for future Canadian copyright policy.

Résumé

L'ère numérique remet en question, plus que jamais auparavant, la pertinence de la législation sur le droit d'auteur. Pas un mois ne se passe sans que semble apparaître une nouvelle vague de modèles d'entreprises ou de technologies basés sur l'Internet qui appellent à se demander si John Barlow Perry avait raison lorsqu'il affirmait en 1994 que le droit d'auteur était mort. Les tribunaux entendent des causes prégnantes qui feront jurisprudence pendant les années à venir, alors que les organes de réglementation envisagent pour le cadre législatif d'importantes réformes qui risquent de modifier les rapports de force classiques entre les intérêts des créateurs et ceux des utilisateurs.

Cette communication commence par un survol de l'impact qu'ont sur le droit d'auteur les technologies actuelles et futures de l'Internet. Elle évoque ensuite les plus récentes réformes du droit d'auteur sur le plan international en s'attardant surtout sur les initiatives des États-Unis et de l'Union européenne. À partir de là, elle analyse le cadre législatif canadien en matière de droit d'auteur sous l'angle de certaines causes et politiques récentes comme le poste tarifaire 22, l'exemption accordée aux reproductions pour utilisation personnelle et l'affaire iCraveTV Webcasting. Elle offre en conclusion certaines recommandations sur l'avenir de la politique canadienne du droit d'auteur.

> Plaintiffs have invested huge sums over the years in producing motion pictures in reliance upon a legal framework that, through the law of copyright, has ensured that they will have the exclusive right to copy and distribute those motion pictures for economic gain. They contend that the advent of new technology should not alter this long established structure.
>
> Defendants, on the other hand, are adherents of a movement that believes that information should be available without charge to anyone clever enough to break into the computer systems or data storage media in which it is located.[1]
>
> Judge Lewis Kaplan
> *Universal City Studios, Inc.* v. *Reimerdes*
> August 17, 2000

Introduction

Since its inception, copyright law has attempted to strike a balance between the rights of content creators and those of content consumers. Copyright law encourages the creation of original works by providing creators with a limited monopoly in the work. Limitations on that monopoly can be found in the finite lifespan of the copyright protection as well as in exceptions such as fair use, which were created to encourage the use and dissemination of ideas through the exposure to the works.

As technology has evolved, so too has the copyright balance. In the United States, for example, early copyright laws provided for a fourteen-year monopoly period for a limited number of works. That monopoly period has been significantly lengthened over two centuries whereby copyright holders now enjoy a larger bundle of rights for a period nearly five times as long.

At the dawn of the "digital millennium," copyright law once again faces challenges posed by technological innovation. The newest challenge is a borderless, non-centralized, digital medium of communication B the Internet. Within the confines of cyberspace, unlimited perfect

copies of works can be generated and disseminated globally in mere seconds, creating the promise of unprecedented access to information.

The benefits of the Internet do not come without a price, however. Presently, once a copyrighted work has been posted on the Internet, the copyright holder typically loses control over it. The work can be replicated, altered, and disseminated by virtually anyone in cyberspace, creating the prospect of widespread copyright infringement.

In light of these technological developments, was John Perry Barlow correct when he proclaimed in 1994 that copyright was dead?[2] If not dead, is the copyright balance in need of yet further amendment?

Policy makers around the world are now grappling with precisely this issue. International treaties have provided the impetus for the United States to enact the *Digital Millennium Copyright Act*[3] and the European Union to respond with its own *Copyright Directive*.[4] In Canada, only four years after its last substantial revision, the *Copyright Act*[5] may be headed toward another round of change.

This paper seeks to address this issue by providing a Canadian perspective on both sides of the balance B the current state of Canadian copyright law and the current state of the Internet and digital technologies. The paper argues that Canada should not blindly follow the U.S. and European approaches but rather ensure that its own effective balance is maintained. If Canada legislates too quickly, it risks upsetting the carefully crafted balance by shifting it towards copyright holders at the expense of fair use.

The potential for a dramatic shift toward copyright holders stems from, in large measure, the gross underestimation of the power of technology. In recent months, new Internet-based technological developments have been increasingly cast as the tools of piracy, fuelling a general perception that a "Wild West" mentality exists online in which users actively engage in the illegal exchange of copyrighted works. Such a perception is unlikely to continue for much longer, however, as copyright holders actively pursue the development of rights management technologies that may eventually provide more control than existing copyright law ever intended.

This paper is organized into three parts. Part One, the Dawn of the Information Age, examines technologies such as peer-to-peer distributive networking and digital rights management, which have a profound effect on copyright today.

Part Two, Canadian Copyright Law in the Information Age, considers a "made in Canada" solution in light of the discussion on recent technological developments. The paper argues that Canadian policy is more advanced than is typically appreciated and that it can deal effectively with challenging issues created by cases such as Napster and iCraveTV.

Part Three, Future Policy Directions, emphasizes the need for a deliberate copyright reform process that is carefully structured to maintain the balance between content creators and content consumers.

Part One — The Dawn of the Information Age

The central consideration when examining the interface between copyright law and technology is the digitization of information. It is commonly known that every piece of digital information is nothing more than a lengthy series of 1's and 0's. To copy the digital information, the string of binary digits needs only to be reproduced. These reproductions do not suffer any degradation to the copy since each copy is identical to the original. The same cannot be said for analog reproductions since with analog duplications, copies are never identical to the original. In fact, each subsequent copy made from a copy degrades even further until a point is reached when no further copies can be effectively made.

Digital information also allows for an infinite number of copies to be made without incurring large costs. The amount of storage media becomes the only limiting factor when dealing with information in digital form. Furthermore, through the use of the Internet, these copies can be quickly disseminated around the globe in a matter of seconds to an unlimited number of people.

Many of the recent technological advancements have been charged with altering the traditional copyright law balance between the protection of creators and the rights of users. Lost in the discussion,

however, is an appreciation for *both* the copyright limiting and copyright enhancing effects that technology provides.

i. New Technologies and their Impact on Copyright Law

a. Peer-to-Peer Distributive Networking

Peer-to-Peer ("P2P") distributive networking has developed into one of the most discussed technologies in recent months. Spurred by the popularity of Napster, it has upset the cyberspace status quo, by permitting users to access each other's files on the Web without the need to establish dedicated Web servers.

Interestingly, P2P networking is not a new concept as it has always been part of the UNIX operating system and its descendants. In the early 1990s, LANtastic offered an inexpensive P2P networking alternative to the traditional dedicated server topology that Novell and others offered for MS-DOS based personal computers. Some time later, Microsoft's Windows v3.11 for Workgroups became the first Windows operating system to offer P2P capabilities. From that point, P2P networking has been a standard feature of the Windows operating system.

The Web, however, is not inherently a P2P system. For the most part, the Web implements a standard client-server interface. Web servers are responsible for hosting Web sites and for providing file storage. Users connect to the Web using either a dial-up or dedicated connection. Once connected to the Internet, users are able to interact with Web servers, much in the same way a node on a LAN would access a file server. Users cannot, however, access the files of other connected users.

P2P changes the existing Web paradigm. Web users are now not restricted simply to the information posted to Web sites since information can be transferred directly between users rather than requiring that information first be uploaded to a third party server. Every user, acting simultaneously as a client and a server, can access vast amounts of previously unavailable information.

Napster,[6] with 40 million users worldwide, is often seen as the impetus for the current P2P craze since it is the original centralized P2P network system for MP3 files.[7] Napster brought P2P further into the

limelight through its ongoing battle with the Recording Industry Association of America ("RIAA").[8]

At the heart of Napster's system is a collection of centralized servers which maintain a record of users that are logged into the system. In addition, a listing of the user's locally available MP3 files is added to Napster's active file listing. Although it generates the user's file list, Napster does not actually store any of the MP3 files. Through the use of the interface search tool, users can locate MP3 files across the Napster system. The interface facilitates a P2P transfer of the file between the user who is hosting the file and the user who requests the file. To augment the search tools and the proprietary file transfer protocol, the newest version of Napster offers users the opportunity to communicate through the use of instant messaging and chat rooms.

Napster is not alone in offering P2P file sharing. For example, Gnutella is another distributed networking protocol that allows P2P file sharing. Originally conceived by NullSoft, a subsidiary of America Online ("AOL"),[9] Gnutella has evolved into an open-source protocol since AOL terminated the project in 1999.[10] Each system is both a server and a client. Unlike Napster, there are no centralized servers that track files on the system.

Gnutella can be viewed as a mesh of computers. Users join the mesh by first connecting to a well-known server and then manually connecting to others. Once a user joins the mesh, the network is flooded with information about it. Each recipient responds to the new user with information about itself. As a result, the new user joining the mesh knows how to connect to everyone else. In order to perform a search, the mesh is flooded with a search message generated by the user. If a particular user has the information requested, it returns a message stating that it has the file, providing the user with the pertinent location.

Freenet,[11] or the Free Network project, is a distributed file publication system first developed by Ian Clarke at the University of Edinburgh. The system was initially conceived as a method of promoting anonymous communication but has now moved beyond its original vision into P2P networking. The system is part of an open source code project and as a result, no one person or entity can be tied to the system.

In Freenet, each node, or computer within Freenet, has a cache of files and each file has a name. Nodes connect to each other in a mesh, similar to Gnutella. Nodes are permitted to place files in their cache or any of their neighbours' caches. If a user needs a file not found within their node's cache, it asks their neighbour for the file. If the neighbour has the file, it transfers the file to the requesting node. If the neighbour does not have it, the host asks its next neighbour and so on. As a result, a depth-first search is performed rather than a broadcast search such as in Gnutella.

b. Real-time Broadcast

As processing speeds and communication bandwidth have increased, so too has the potential to broadcast multimedia programs across the Internet. RealNetworks[12] developed an application that makes it possible for both audio and video to be "streamed" from a broadcast site to users. The free application known as RealPlayer allows for radio and television stations to broadcast the streamed material over the Web.

Implementing this new technology, iCraveTV became the first Internet equivalent to a cable television provider in November 1999. At the time of its debut, iCraveTV enabled users to watch 15 channels[13] directly by using his/her personal computer.[14] The broadcasts were picked up through an antennae located atop a north Toronto building. The signal was transformed into a retransmission signal, digitized, and then streamed onto the Internet. The end user accessed the iCraveTV signal by using their personal computer, the RealPlayer application and an Internet connection.[15] Although iCraveTV has ceased broadcasting,[16] it provided a small glimpse into the overall potential of the multimedia "streaming" technology.

c. Digital Rights Management

Digital rights management ("DRM") has moved to the forefront of the battle with information content piracy. DRM systems provide copyright holders with the ability to build limitations into the digital code of various file formats. With these limitations in place, copyright holders can maintain complete control over the distribution and

copying of their work and can ensure that their rights, pursuant to s. 3 of the *Copyright Act*, are not jeopardized.

Led by companies such as Preview Systems,[17] InterTrust,[18] RightsMarket,[19] Alchemedia,[20] Sunhawk,[21] Reciprocal,[22] and ContentGuard,[23] the majority of DRM developers have created systems that are similar in function and features, though proprietary technology is used in each case. These comparable systems encode the information content and then provide a facility to manage the rights or licences associated with each piece of information content. For example, the technology enables a copyright holder to set limits on the use of their information content, such as the number of copies that may be made or for how long the information may be used.

With the proliferation of DRM technologies, compatibility issues and the long-term viability of certain companies create numerous complications in attempting to establish a unified front in the battle against unauthorized use and piracy. Many members of the recording industry and the consumer electronics and information technology industries have founded a forum in order to develop open-technology specifications for protected digital music distribution. This forum, known as the Secure Digital Music Initiative[24] ("SDMI") is to proceed in phases, with the technology slowly integrated into existing systems. However, SDMI has illustrated the difficulty in developing a uniform standard as compromise has led to a number of delays, which in turn, has resulted in further diminished copyright holder control.

d. Application Service Providers

For most software developers, the unauthorized duplication of their products was long considered a cost of doing business. Attempts were made to incorporate copy protection into software, but these proved to be unsuccessful. Today, the computer software industry has "waved the white flag" and budgets for a thirty percent software piracy rate.[25]

To combat software piracy, most software developers have focused on larger licensing agreements with companies. A growing number of software developers are beginning to reconceive how they do business and in the process are addressing lingering piracy concerns. The birth of the Web, the increasing availability of broadband, and the

potential to create more robust online applications has allowed many companies to re-invent themselves as application service providers ("ASP") by developing pay-per-use services.

Consider a new online software service offered by Adobe, the company responsible for making PDF the standard in document transmission on the Web. Although Adobe freely distributes Acrobat, its PDF reader, until now the software needed to make PDF files had to be purchased from the company.

Like any other software program, Adobe Acrobat was susceptible to duplication since a purchased software CD could easily be copied and distributed on the Internet or burned onto blank CD's and sold illegally. Adobe recently adopted a new business model for its PDF creation program by functioning as an application service provider (ASP). The change means that PDF document creation is now offered as a Web service with Adobe retaining greater control over the distribution of its software. Rather than purchasing the software program, users can convert their documents into PDF format online, directly through the company's Web site. Adobe is currently offering users three free conversions each month, with unlimited usage set at US$9.99 per month or US$99.99 for the year. By moving toward an ASP model of distribution, Adobe is able to control the use of the software and to cut down on the likelihood of software piracy.

Adobe is but one example of a trend that is likely to sweep across the software industry. By eliminating the user's ability to duplicate the original information content, unauthorized use and piracy can be severely undermined.

ii. Technology and Copyright: The Pendulum Swings Back and Forth

Although there is a tendency to cast technology as "good" or "bad," most technologies are better appreciated as neither "good" nor "bad" but simply "neutral" since it is the application of the technology that creates its beneficial or deleterious effects. While technologies such as P2P, DRM, and ASPs are often viewed as compromising or enhancing copyright protection, the dual application of these technologies must be

considered. The following section considers several broader issues when addressing some of the aforementioned new technologies.

a. Peer-to-Peer Distributive Networking

At the heart of the Napster case is the question of control. Napster maintains that it functions strictly as a conduit and does not have control over the content exchanged by its users. Although at first glance there may be merit to this argument, a closer examination of the Napster software reveals that the company has greater control than it typically acknowledges.

When a user logs into the Napster system, the software uploads a list of the MP3s available to share with "Napster community." For each song on the list, the software first calculates its own unique identifier, using MD5 hash algorithm.[26] These identifiers are then included on the list when it is uploaded to the Napster servers.[27]

Since each song has an associated unique identifier, Napster could introduce functionality in its software that would check the identifier against a database of identifiers provided by the music industry. If a match occurred, the software would refuse the transfer, thereby providing Napster with the power to filter out copyrighted material.

The exchange of MP3 files through Napster has invariably shifted the focus of P2P discussion toward piracy issues and the use of the technology to conduct unauthorized transfers of copyrighted material. Often overlooked, however, are the other beneficial uses for the technology. For example, P2P can also be used to transfer files in the public domain, files with open-use licensing provisions, or files that are simply of a personal nature.

In addition, P2P enables any computer with Internet access to function as a server. This creates new opportunities for publishing and the establishment of communities and workgroups. P2P technology may alter the traditional Web paradigm by providing individuals a new avenue to exploit their work and avoid the traditional content aggregation found in Web portals.[28] It may spur an evolution towards a more decentralized model, in which information is not found in one particular location but rather pushed out to individual users and content creators. The technology may also provide developing countries with the ability

to further expand their computer infrastructure by enabling desktop personal computers to be used as servers rather than relying on expensive, dedicated Web servers.

Systems such as Freenet were conceived as tools of free speech. In a centralized Internet model, information content is more susceptible to control or censorship by targeting the central source. Freenet makes it impossible to do that, since even if the information content can be located, additional copies likely exist elsewhere within the system. Moreover, identification of the poster is rendered difficult, if not impossible.

Finally, the challenge of regulating P2P systems cannot be overstated. Although shutting down centralized servers in an attempt to regulate systems such as Napster may be possible, decentralized systems such as Gnutella and Freenet are impossible to control.

b. Digital Rights Management

DRM is held out by many as the saviour technology for copyright holders when dealing with the problems associated with the preservation of copyright in the digital age. Although DRM may provide new protections, the long-term use could actually swing the pendulum too far in the opposite direction, by eliminating user rights.

By using DRM technology to eliminate any copying of a work, copyright holders may, in the process, take away rights from users that are clearly permitted under the law. For example, many users make use of the fair dealing exceptions when they routinely and legally copy portions of a text for research or study purposes.[29] These users might find themselves unable to make copies since the DRM technology might prohibit all copying of the electronic text.

As the Internet becomes an increasingly prevalent part of society, content in a digital form will emerge as the norm rather than the exception. In order to ensure that content is safe from the threat of piracy, DRM technology will be utilized at every opportunity. Although the entertainment industry is highly sensitive to potential for piracy,[30] many believe that the recently enacted *DMCA* has the potential to curtail "uses of lawfully acquitted materials traditionally sanctioned by law."[31]

With the increased use of DRM technologies, it is likely that access privileges originally enjoyed under fair-use and other statutory limitations will be significantly reduced. While fair use remains as a defence to copyright infringement in the U.S., it will not constitute a valid defence to the circumvention of DRM technology. Consequently, the *DMCA* may have introduced a new "right of access" into U.S. copyright law.

A "right of access" runs afoul of the original intent of U.S. copyright law — to secure "exclusive rights" for "limited times" "to promote progress." It was never envisioned that copyright holders were to have unlimited control over the access to their works. As the U.S. Supreme Court has noted:

> The limited scope of the copyright holder's statutory monopoly, like the limited copyright duration required by the Constitution, reflects a balance of competing claims upon the public interest: creative work is to be encouraged and rewarded, but private motivation **must ultimately serve the cause of promoting the broad public availability of literature, music and the other arts**. The immediate effect of [Y] copyright law is to secure a fair return for an "author's" creative labor. But the ultimate aim is, by this incentive, to stimulate artistic creativity for the general public good.[32] [Emphasis added]

Copyright holders, wielding the shield of DRM technology and the sword of the *DMCA*, may now be able to carve the heart right out of the copyright law balance. The long-standing doctrine of fair use may be facing the inevitable consequence of being usurped by the "digital millennium" doctrine affectionately known as "pay-per-use."

Part Two — Canadian Copyright Law in the Information Age

i. A Historical Perspective

The first Canadian copyright legislation was enacted in 1924,[33] based largely on the British Copyright Act of 1911.[34] In 1957, the Isley Commission — the Royal Commission on Patents, Copyright,

Trademarks and Industrial Design — was charged with the responsibility to conduct the first studies into Canadian copyright reform. The Commission emphasized the underlying principle of Canadian copyright law — the balance of rights between creators and users in an "incentive versus access" policy framework. The recommendations set out by the Commission were never acted upon; however, they continue to remain influential in the development of Canadian copyright law.[35]

The 1970s saw a rejuvenated interest in copyright reform. Two studies further examined the issue: the Economic Council of Canada's *Report on Intellectual and Industrial Property*,[36] and the Keyes and Brunet Report, *Copyright in Canada — Proposals for Revision of the Law*.[37] Between 1980 and 1983, the Department of Consumer and Corporate Affairs in conjunction with the Department of Communication commissioned the "Copyright Revision Studies" — fourteen studies into various aspects of copyright reform such as "fair dealing," private copying, competition and Canadian culture, copyright collectives and the effect on copyright. A strong emphasis on economic considerations was apparent in all the studies.

From Gutenberg to Telidon,[38] a copyright reform white paper based on the Copyright Revision Studies, was delivered in 1984. A change in government buried the policy for a short time; however, it resurfaced and formed the basis of the newly formed Standing Committee on Communications and Culture. The Committee concluded that "the *Copyright Act* is seriously outdated, that copyright must continue to be regarded as private property, that revisions must respond to technological changes and that new rights and subject matters are now essential."[39]

After three decades of studies into the question of reform, the *Charter of Rights for Creators*[40] became the official blueprint for copyright reform in Canada, establishing the policy platform that underlies the current multi-phase reforms. The document outlined a plan for a multi-phase revision of Canadian copyright law.

The Phase One amendments were introduced into the House of Commons as Bill C-60 in 1987. In 1988, the amendments became law, extending copyright protection to computer programs,[41] strengthening the concept of an author's "moral rights" within Canadian law,[42]

increasing penalties for copyright infringement,[43] and permitting copyright collectives to collect royalties on behalf of its authors.[44]

Following the Phase One amendments, incremental changes were made to the copyright law, as Canada sought to fulfill its international treaty obligations including the *Canada-U.S. Free Trade Agreement*,[45] the *North American Free Trade Agreement* ("NAFTA"),[46] and the *World Trade Organization Agreement*.[47] Each treaty required minor revisions to be made to the existing copyright regime in order to ensure that Canada was fully compliant with its international obligations.

Phase Two of the multi-phase reform plan was enacted in 1997. Commonly referred to as Bill C-32, Phase Two included many technical amendments such as exemption clarifications for disabled persons[48] and for non-profit institutions such as universities, libraries, archives and museums.[49] The two most important changes had a direct effect on the music industry. "Neighbouring rights" on sound recordings were established for the first time in Canada.[50] In addition, a tariff on blank audiocassettes was instituted in conjunction with a private copying right.[51] These two provisions harmonized Canadian copyright law with the *Rome Convention* of 1961.[52]

Although the recent reports and amendments to the *Copyright Act* have reinforced the economic notion of copyright, the concept of personal rights maintains a strong presence within Canadian policy. It is important to note that two ministries — Heritage Canada and Industry Canada, jointly administer copyright law in Canada, each reinforcing one of the two underlying philosophies of copyright. Moreover, the French version of *Copyright Act* continues to pay homage to the European ideal as it is titled "*Droit d'auteur*," once again reinforcing the notion of personal rights. With the enactment of Bill C-60 in 1988, Canadian copyright law took a step away from the prevailing economic view of copyright law that has been central to many of the world's common law jurisdictions. The introduction of "moral rights" into the legislative framework moved Canada again towards the European view of copyright as a personal right. The "tug-o-war" between economic and personal rights that exists at the centre of Canadian copyright policy has been an essential factor in maintaining an effective balance

between the rights of the content creator and the rights of the content consumer.

As Canada prepares for Phase Three of copyright reform, it faces a critical policy decision. Do the Internet and new technologies such as P2P, real-time Internet broadcasting, and DRM alter the copyright balance? If so, in what direction? A determination of that issue will provide Canadian policy makers with the roadmap for future regulatory initiatives. As discussed in part one, the impact of new technology is not absolute nor as clear cut as is often perceived. Before acting hastily, Canadians should consider whether the current system might actually be sufficiently flexible to adequately address these new challenges. In the section that follows, the application of Canadian law to two of the most notorious and complex new Internet businesses — Napster and iCraveTV — is assessed.

ii. Copyright Reform in Canada: Desperate Measures or Technical Measures

a. Napster North of the Border

In just over a year, Napster has emerged as one of the Internet's greatest success stories and most remarkable phenomenon. The file sharing program now boasts 40 million users with a million simultaneous users at peak times. The opportunity to share music with millions of users has revolutionized the music industry, threatening the business model of established recording companies and leading to a plethora of high-profile litigation.

Although it is unclear whether Napster is legal under U.S. copyright law, the case would be quite different if argued in a Canadian court. With contributory copyright infringement and substantial non-infringing use a critical part of the U.S. legal lexicon, the case turns on legal issues that are not part of the Canadian copyright law framework. Instead, a Canadian analysis would turn to the recent Tariff 22 decision, which provides considerable guidance on how Napster and its users would fare in Canadian court.

Pursuant to s. 67 of the *Copyright Act*, the Society of Composers, Authors and Publishers of Music of Canada ("SOCAN") filed with the Canadian Copyright Board statements of proposed royalties for the

public performance, or the communication to the public by telecommunication, in Canada, of musical or dramatico-musical works for the years 1996 to 1998. The proposed tariffs included a tariff for the "Transmission of Musical Works to Subscribers Via a Telecommunication Service Not Covered under Tariff No. 16 or 17". This tariff, widely known as Tariff 22, targeted the communication of musical works by means of computers of other devices connected to a telecommunications network where the transmission of those works can be accessed by a person independently of any other, namely the Internet.

In a previous ruling, the Canadian Copyright Board decided to review the proposed tariff in two phases. Phase I aimed to address a number of legal issues[53], while Phase II was intended to address the policy issues raised by Tariff 22. In Phase I, the Canadian Copyright Board determined which online actions trigger liability under the *Copyright Act*, thus necessitating the establishment of a tariff.[54]

In the *Tariff 22* decision, the Canadian Copyright Board undertook a thorough analysis of the current legal regime in Canada. Tackling the issues created by the recent technological revolution, the Canadian Copyright Board arrived at ten legal conclusions [hereinafter *CCB Conclusions*] based on the issues raised during the hearing. In particular, the Canadian Copyright Board concluded:

1) A musical work is not communicated when it is made available on a server.
2) A musical work is communicated by telecommunication when a server containing the work responds to a request and packets are transmitted over the Internet for the purpose of allowing the recipient to hear, see or copy the work.
3) The public or private character of a communication over the Internet can be determined according to established legal principles.
4) A communication need not be instantaneous or simultaneous to be a communication to the public.
5) By making the work available, a person authorizes its communication.

6) The person who made a work available communicates it when it is transmitted from any server.
7) Persons who can avail themselves of paragraph 2.4(1)(b) of the Act with respect to a given communication of a work do not communicate the work. Generally speaking, this includes all entities acting as Internet intermediaries such as the ISP of the person who makes the work available, persons whose servers act as a cache or mirror, the recipient's ISP and those who operate routers used in the transmission.
8) An entity cannot claim the benefit of paragraph 2.4(1)(b) with respect to a given communication of a work if the relationships it entertains with the person who made the work available are such that it can be said to act in concert with that person or if it does not confine itself to the role of an Internet intermediary.
9) The person that creates an embedded hyperlink to a work authorizes its communication. The person that merely supplies a link, which must be activated by the user, does not.
10) Communications occur at the site of the server from which the work is transmitted, without regard to the origin of request or the location of the original Web site. Therefore, to occur in Canada, a communication must originate from a server located in Canada on which content is posted. In the same vein, the communication triggered by an embedded hyperlink occurs at the site to which the link leads.

Although these conclusions clarify the breadth and scope of Canadian copyright law in light of the many recent technological innovations occurring in "cyberspace," they may serve an even greater significance within the larger scope of copyright reform. While many jurisdictions such as the United States, the European Union, and Australia have been quick to amend their copyright laws, Canada has adopted a "wait and see" approach. The *Tariff 22* decision may be seen

as a vindication for current government's copyright policy since the *CCB Conclusions* were arrived at without the need for further amendments to the *Copyright Act*.

As previously discussed, unlike the *DMCA*, which establishes a complex set of rules when dealing with the issue of Internet Service Provider ("ISP") liability,[55] *Tariff 22* demonstrates that in many instances complex amendments may not be the best solution. In fact, the existing laws may prove to be adequate to meet future challenges posed by the proliferation of digital technologies. Although many of the arguments raised in the Napster case are based around concepts not found in Canadian copyright law, the facts nevertheless provide a perfect opportunity to evaluate the effectiveness of the *CCB*.

Conclusions

In the U.S., Napster has argued it is the equivalent of an ISP and thus entitled to an exemption of liability under the *DMCA*. Pursuant to Canadian law, the Canadian Copyright Board ruled that ISPs could rely upon s. 2.4(1)(b) of the *Copyright Act*.[56] The section exempts intermediaries from copyright liability provided that they function strictly as a conduit in the transfer of data. Where an ISP assumes a greater role — for example, where it posts content itself or takes steps to modify or block content of its users — it ceases to function as an intermediary. Consequently, the ISP in that situation would face liability as a party to the copyright infringement.

The Canadian Copyright Board alluded to the fact that services such as Napster would at least be protected from charges that they authorize their users to commit copyright infringement, a powerful argument in the U.S. The Board held that:

> [...] Even knowledge by an ISP that its facilities may be employed for infringing purposes does not make the ISP liable for authorizing the infringement if it does not purport to grant the person committing the infringement a license or permission to infringe. An intermediary would have to sanction, approve or countenance more than mere use of equipment that may be used for infringement. Moreover, an ISP is

> entitled to presume that its facilities will be used in accordance with the law.[57]

Consequently, simply knowing that its facilities might be used to infringe copyright does not render the ISP liable, so long as it has not actually sanctioned the copyright infringement.[58] A centralized P2P system such as Napster would likely qualify for this exemption.

The copyright balance is effectively maintained, however, as users of a P2P system could not rely on the same ISP provisions to absolve themselves of liability. As noted above, a P2P system has the effect of transforming each client computer into a server. Copyright holders control not only the right to use a work, but also the right to authorize its use.[59] In the *Tariff 22* decision, the Canadian Copyright Board held that an authorization to communicate occurs as soon as the information content is posted on an Internet-accessible site. Accordingly, copyright liability attaches from the moment the content appears on a Web site, or is made available through the P2P system. In order to make information content available, each user would require appropriate licensing agreements to ensure compliance with the *Copyright Act*.

Moreover, recent amendments to the *Copyright Act* include a private copying right which ensures that users may be seen as paying for the music they copy. The private copying right expressly legalizes copying sound records of musical works onto recording media such as audiocassettes or CD-R for the private use of the person that makes the copy.[60]

To compensate for this right to make private copies, a new tariff is levied on the sale of blank audio recording media to compensate authors, performers, and the makers of sound recordings. Contrary to popular belief, the definition of blank audio recording media is not limited to audiocassettes and CD-R. In fact, the tariff may be applied to the sale of any media capable of being used to make private copies including computer hard drives and MP3 players.

The private copying tariff is compensatory in nature. Accordingly, tariff rates are set to ensure that copyright holders are adequately compensated for lost revenues due to private copying. Should the popularity of music swapping through P2P systems continue to increase, the

applicable tariff would presumably increase to address the revenue losses. However, should DRM technologies or online music licensing emerge as viable alternatives that lead to a decrease in private copying, the tariff may also be lowered.

Moreover, in a 1996 decision involving royalties for "muzak" played in stores, the Canadian Copyright Board clearly indicated that compensation for the primary use of the music should be treated as adequate compensation regardless of whether there may be other incidental uses. In particular, the board argued that:

> The copyright owner is fully compensated for the use of the music by the payment of the royalty that is set for the purposes of the principal use (the performance in the store) irrespective of whether or not a prior, incidental use (the communication to the store) is involved in the process. Any value to the composers is already accounted for by setting the price based on the purchaser's use.[61]

This reasoning suggests that the Canadian Copyright Board will be reluctant to compensate copyright holders for secondary uses of the work where they receive adequate compensation from tariffs levied on the primary uses of their work.

To complicate the matter further, contradictory economic evidence exists for assessing lost revenues. While the recording industry starts with the assumption that private copying results in lost revenues, supporters of private copying argue that the practice may actually increase revenues. They note that private copying may be better viewed as "sampling" that provides music enthusiasts with exposure to a wider range of music that ultimately leads to increased sales. Buttressing this argument, a recent Canadian study found that Canadian Napster users are above average music buyers who actually influence others in the purchase of music.[62]

To a certain extent, users who avail themselves of P2P systems can be seen as paying for the information as a result of the private copying tariff. The money that is collected is redistributed, through a collective, to the rightful copyright holders. In fact, since music sharing

online might actually result in increased sales, copyright holders might be overcompensated for their work under the private copying system since they would receive tariff revenues from the sale of blank media and not suffer a corresponding loss of sales revenue.

b. iCraveTV

As noted above, at the time of its debut in November 1999, iCraveTV enabled users to watch 15 channels[63] directly on their personal computer.[64] The broadcasts were picked up through an antennae located atop a north Toronto building. The signal was transformed into a retransmission signal, digitized, and then streamed onto the Internet. The end user accessed the iCraveTV signal by using their personal computer, the RealPlayer application and an Internet connection.[65]

The iCraveTV litigation brought the retransmission exception found in the *Copyright Act* under closer scrutiny. In Canada, s. 31 of the *Copyright Act* governs the retransmission of broadcast signals. In particular, s. 31(2) provides as follows:

> It is not an infringement of copyright to communicate to the public by telecommunication any literary, dramatic, musical, or artistic work if:
>
> a) the communication is a retransmission of a local or distant signal;
> b) the retransmission is lawful under the *Broadcasting Act*;
> c) the signal is transmitted simultaneously and in its entirety, except as otherwise required or permitted by or under the laws of Canada; and
> d) in the case of retransmission of a distant signal, the re-transmitter has paid any royalties, and complied with any terms and conditions, fixed under this Act.

A. Legislative and Judicial History Behind s. 31(2)

In assessing the application of s. 31(2), insight can be drawn from a historical analysis of the copyright disputes that arose in the infancy of the cable industry. These disputes between local television broadcasters and cable companies revolved around the issue of whether copyright liability could be triggered by the retransmission of over-the-air local broadcast signals.[66]

In Canada the question of copyright protection of television broadcasts was first addressed in *Canadian Admiral Ltd. v. Rediffusion.*[67] In this instance of retransmission of a live broadcast, the courts afforded little in the way of copyright protection, a holding that was to become indicative of Canada's future policy position on this issue.

After the emergence of cable broadcasting in the late 1960s, the CRTC considered its impact on Canadian broadcast policy on a number of occasions. In 1969, the Commission issued a statement recognizing the growing importance of cable television.[68] It argued that cable facilitated and encouraged local programming, recognizing that it should complement, rather than compete with programming available to the community through television. It also recognized the need to license all systems and to evaluate their relation with television.

In July 1971, the CRTC released its *Policy Statement on Cable Television: Canadian Broadcasting B A Single System'*.[69] In that statement, it took note of the importance of copyright, but argued:

> ...the concept of copyright is somewhat limited in the context of television-cable relationship and in some respects it might be detrimental to look solely to copyright as a systematic solution to the problem of achieving equity between these two segments of the broadcasting system.
>
> The Commission believes that it is imperative that the broadcasters and the cable television operators develop a method that will correct the inequity that has developed in the system. However, if no solution is forthcoming, the Commission will take necessary steps to achieve this goal.[70]

Accordingly, rather than using copyright to bar retransmission by the cable companies, the CRTC approach to the issue of cable retransmission focused on balancing the benefits to Canadian broadcasting policy on the one hand with the need for fair compensation on the other. The Commission navigated through this balance by advocating an industry-led solution based on a negotiated compensation settlement.

The Supreme Court weighed in on the issue of retransmission several years later in *Capital Cities Communications Inc. v. CRTC*.[71] At issue was the jurisdictional reach of the CRTC and the right of cable companies to alter retransmitted programming by inserting their own commercial messages, a practice the CRTC approved in its 1971 report.[72] On the matter of jurisdiction, Chief Justice Laskin ruled that:

> I am therefore in no doubt that federal legislative authority extends to the regulation of the reception of television signals emanating from a source outside of Canada and to the regulation of the transmission of such signals within Canada. Those signals carry the programmes which are ultimately viewed on home television sets; and it would be incongruous, indeed, to admit federal legislative jurisdiction to the extent conceded but to deny the continuation of regulatory authority because the signals are intercepted and sent on to ultimate viewers through a different technology. Programme content regulation is inseparable from regulating the undertaking through which programmes are received and sent on as part of the total enterprise.[73]

With regard to the alteration of retransmitted programming, the Court overturned the CRTC policy, ruling that such activity was not permissible since it did not allow the broadcasting station to retain the commercial value of its programs. Implicit in the decision, however, was the understanding that unaltered retransmission was permissible and not a violation of copyright.

In March 1983, the CRTC again resisted the use of copyright to bar retransmission by emphasizing the need for a negotiated settlement. In its Decision 83-126, the Commission stated that it "recognizes that in

certain circumstances at the local exhibition phase, various problems may arise related to the issue of potential copyright infringement and the associated issue of broadcaster consent'. The Commission expects the parties involved to take steps to make such contractual or other arrangements as may be necessary in such circumstances."[74]

The issue of redistribution of foreign signals without payment was largely resolved through the enactment of section 2006 by the *Canada-United States Free Trade Implementation Act* in 1988, which led to the introduction of s. 28.01 of the *Copyright Act*, now s. 31.[75] Section 2006 mandated that each country's copyright law include a right to remuneration for retransmission subject to certain conditions. Given the absence of any prohibition against retransmission, the agreement between Canada and the United States does appear to accept the premise that retransmission is permissible where it meets the standards now contained in s. 31 (2) of the Copyright Act.

The Canadian courts had the opportunity to consider the new section in *FWS Joint Sports Claimants v. Canada (Copyright Board)*,[76] a 1991 Federal Court of Appeal decision. That case stemmed from a challenge to the new royalty scheme by a group of royalty collectives, including professional sports leagues and various cable and broadcaster associations. The Federal Court of Appeal upheld the royalty scheme, noting that "this was its first consideration of the amendments to the *Copyright Act*, R.S.C. 1985, c. C-42, which were enacted pursuant to the Canada-United States Free Trade Agreement Implementation Act (S.C. 1988, c. 65). Prior to the passage of this legislation, there were no royalties payable by those who retransmitted these distant signals, which lacuna in the law was filled by the new legislation."[77]

As reflected by the case law and the legislation, in order to harness associated dynamic efficiencies, Canada has to date taken a minimalist approach to the regulation of copyright and retransmission of broadcast signals through cable transmissions. Given Canada's minimalist approach to the regulation of e-commerce and the information highway, it appears likely that this approach will continue with respect to retransmission of broadcast signals through the Internet.

B. Application of s. 31(2) to iCraveTV's Activities

In order to qualify for the retransmission exemption found in s.31(2) of the *Copyright Act*, a re-transmitter must meet all four provisions contained in the section.

Subsection (a) requires the communication to be a retransmission of a local or distant signal. As described above, iCraveTV captured local and distant signals via antennae, tuned the signal into a retransmission signal, digitized it, and then streamed it onto the Internet. This process would qualify under the subsection since the provision speaks only to the origin of the retransmitted signal.

Subsection (b) mandates that the retransmission is lawful under the *Broadcasting Act*.[78] The CRTC's recent exemption order for new media companies[79] exempts Internet audio and video broadcasts of the nature of iCraveTV from regulation, thus rendering the activity lawful under the *BA*.

Subsection (c) provides that the signal must be retransmitted simultaneously and in its entirety, except as otherwise required or permitted by or under Canadian law. This provision is particularly important as it precludes the deletion of advertising material or time shifting to allow for receipt of programming from different time zones.

This was the most difficult provision of the four for iCraveTV to establish. Although it is possible to assume that they retransmitted the signal simultaneously and in its entirety, critics argue that iCraveTV was unable to meet the requirement of this provision since it converted the original broadcast signal into a digital signal.

Subsection (d) establishes the royalty payment scheme for retransmission. Upon payment of the prescribed fees and royalties, these provisions create a statutory right to publicly retransmit a broadcast signal. At the present time, there are no fixed royalties for Internet retransmissions. Since the provision only requires payment of applicable royalties, iCraveTV was in compliance with this provision as well.

Interestingly, iCraveTV recognized the need to establish a royalty scheme for Internet retransmission as a means to legitimize its activities and to modernize the current framework. The company applied to the Canadian Copyright Board to commence proceedings into the establishment of such a royalty.[80] The proceedings were actually opposed by

the broadcasters and content creators who demanded that the royalty application be withdrawn as part of the eventual settlement.[81]

Although the applicability of this exception to iCraveTV has never been formally established, the recent rumblings from the Canadian Association of Broadcasters ("CAB") suggest that the exemption would likely capture online retransmissions.[82] Michael McCabe, President of the CAB, recently stated that the "loophole" created by s. 31 of the *Copyright Act* should be eliminated as it pertains to online retransmission, seemingly acknowledging that the *Copyright Act* permits retransmission activities on the Web.

Part Three — Future Policy Directions

With the continual evolution of the Internet, of its community of users, and of its technology, it is a dangerous practice to speak in absolutes when it comes to the digital environment and copyright law. Change is constant in an online environment. Experts presenting evidence at the Tariff 22 hearings as to the continuing evolution of the Internet did not have the clairvoyant abilities to predict the current state of development. Instead, from their evidence, the Canadian Copyright Board had the conceit to conclude, "that there will likely not be any significant changes in the near future in the basic activities involved in Internet transmissions."[83] It is obvious from such a statement that the technology and its future incarnations are at best difficult to predict. As evidenced by recent developments such as P2P and DRM, there are technologies that are capable of both enhancing and limiting copyright protection.

As the technologies continue to evolve, the Canadian copyright system is under siege. The CAB wants to eliminate the "loophole" found in the *Copyright Act*.[84] *SOCAN has filed an appeal of Tariff 22*.[85] In addition, Canada will be eventually under considerable international pressure to implement the recent WIPO treaties. Finally, the success of the "notice and take down" provisions of the *DMCA* may impress upon Canadian copyright holders the need for similar provisions within the Canadian framework.

It is critical that Canada reject such pressures and refrain from aggressively pursuing reforms in the immediate future. With the Internet only recently enjoying mainstream acceptance, the overall effects of these new technologies is as yet undetermined. Providing excessive legal protection at this stage may simply be overkill and drastically alter the copyright balance that currently exists.

Copyright law is not powerless in the face of the ever-changing digital environment. The Canadian experience illustrates that policy changes can be made and implemented with relative effectiveness in a manner that does not tie policy to a single technology or business model. Law should respond to the new technological challenges but it must do so with a measured, balanced approach that preserves the interests of both the content creator and content user communities.

The Internet presents a monumental opportunity for society. Through the use of the Internet, each user becomes his/her own publisher, providing individuals with unprecedented access to free speech. Moreover, greater access to a wider audience creates new avenues for profit for content creators. Technology, which energizes the "digital millennium," is in a constant state of evolution. It is essential that society does not allow the ever consuming "fear of the unknown" to blur this reality and cloud rational decision-making and sound judgment. Reflexive, "knee-jerk" legislation may seem vital in the moment; however, its enduring effects may leave the future of copyright law unbalanced and have a chilling effect on further innovation.

Notes

1. See Universal City Studios, Inc. v. *Reimerdes*, 2000 U.S. Dist. LEXIS 11696 (S.D.N.Y. Aug. 17, 2000) [hereinafter DeCSS Case].
2. J.P. Barlow, "The Economy of Ideas" *WIRED*, March 1994, online: WIRED.com <http://www.wired.com/wired/archive/2.03/economy.ideas_pr.html> (date accessed: 26 August 2000).
3. *Digital Millennium Copyright Act of 1998*, Public Law No. 105-304, 112 Stat 2860 (28 October 1998) [hereinafter DMCA].

4. Common position adopted by the Council with a view to the adoption of a Directive of the European Parliament and of the Council on the harmonisation of certain aspects of copyright and related rights in the information society, Brussels, 14 September 2000, (OR. en).
5. Copyright Act, R.S.C. 1985, c. C-42, as amended [hereinafter CA].
6. See <www.napster.com>.
7. Many variants of Napster have been created to permit the P2P transfer of all file types. Wrapster <members.fortunecity.com/wrapster/> is a variant, which makes use of the Napster network to exchange all types of files by encapsulating them in an MP3-type "wrapper". OpenNap <opennap.sourceforge.net> is a project that functions in the same way as Napster but allows the transfer of all file types without having to modify the files as is done in Wrapster.
8. For interim order, see A & M Records, Inc. v. Napster, Inc., 2000 U.S. Dist. LEXIS 11862 (N.D. Cal. August 10, 2000) [herinafter Napster Case]; the interim order has been stayed, see A & M Records, Inc. v. Napster, Inc., 2000 U.S. Dist. LEXIS 18688 (9th Cir. July 28, 2000).
9. See <gnutella.wego.com>.
10. As Gnutella is an open source protocol, many developers have created their own flavours of a Gnutella-based interface. These include: Gnumm <www.burse.uni-hamburg.de/~mark/gnumm>; ToadNode <www.toadnode.com>; Gnotella <notella.nerdherd.net>; My-Tella <mytella.bizland.com>; N-Tella <www.friedcat.co.uk>; Furi <www.jps.net/willianw/furi>; Gtk-Gnutella <gtk-gnutella.sourceforge.net>; Gnut <www.umr.edu/~jip>.
11. See <freenet.sourceforge.net>.
12. See <www.real.com>.
13. Included were all major Canadian broadcasters (CBC, CTV, Global, City-TV) and a number of U.S. broadcasters (NBC, ABC, PBS, WB).
14. This number grew to 17 within one month as two additional Buffalo channels, affiliates of CBS and Fox, became available.
15. The iCraveTV Web site indicated that users were required to connect to the Internet at minimum speeds of 56k, presumably to ensure reasonable transmission quality.
16. Twentieth Century Fox Film Corp. v. ICRAVETV, 2000 U.S. Dist. LEXIS 1013 (W.D. Pa. Jan. 28, 2000). In the end, a settlement agreement was reached. For the agreement, see online: Canadian Association of Broadcasters <http://www.cab-acr.ca/english/joint/submissions/settlement.htm (date accessed: 26 August 2000).

17. See <www.previewsystems.com>.
18. See <www.intertrust.com>.
19. See <www.rightsmarket.com>.
20. See <www.alchemedia.com>.
21. See <www.sunhawk.com>.
22. See <www.reciprocal.com>.
23. See <www.contentguard.com>.
24. See <www.sdmi.org>.
25. E. Hansen, J. Borland and M. Yamamoto, "Napster wildfire spreads beyond music: Arms race in PC Software", CNET (15 May 2000), online: CNET News.com <http:/news.cnet.com/news/0-1005-201-1757865-2.html> (date accessed: 8 August 2000).
26. MD5 was invented in 1991 by noted cyptographer Ronald L. Rivest. In a four-stage process, MD5 generates a unique 128-bit string for any file, no matter what its size. For further details, see R. Rivest, RFC 1321 <http://www.landfield.com/rfcs/rfc1321.html> (date accessed: 18 October 2000).
27. C. Mann and R. Parloff, "Experts Say Napster, Playing Dumb, Resists Possible Tech Cure for Copyright Infringement", Inside (18 October 2000), online: Inside.com <http://www.inside.com/story/Story_Cached/0,2770,11683_9_12_1,00.html> (date accessed: 18 October 2000).
28. C. Shirky, "Content Shifts to the Edges" <http://www.shirky.com/writings/content.html> (date accessed: 24 August 2000).
29. Copyright Act, supra, s. 29.
30. Fear of a Pay-Per-Use World, supra.
31. Fear of a Pay-Per-Use World, supra.
32. Twentieth Century Music Corp v. Aiken, 422 US 151 at 156 (1975).
33. Copyright Act, 1921, 11-12 Geo. V. c. 24.
34. Copyright Act 1911 (U.K.), 1911, c. 46.
35. Ibid at 2.
36. Economic Council of Canada, Report on Intellectual and Industrial Property. (Ottawa: Information Canada, 1971).
37. Keyes, A. A. and C. Brunet. Copyright in Canada: Proposals for a Revision of the Law. (Ottawa: Consumer and Corporate Affairs Canada, 1977)
38. From Gutenberg to Telidon: A White Paper on Copyright. (Ottawa: Consumer and Corporate Affairs Canada, 1984).
39. A Charter of Rights for Creators, supra at 3.

40. A Charter of Rights for Creators. Report of the Sub-Committee on the Revision of Copyright. (Ottawa: Standing Committee on Communications and Culture, 1985) [herinafter A Charter of Rights for Creators].
41. Copyright Act, supra, s. 2, s. 3(1)(h) and s. 30.6.
42. Copyright Act, supra, ss. 14.1 — 14.2.
43. Copyright Act, supra, Part IV.
44. Copyright Act, supra, Part VII.
45. Canada-United States Free Trade Agreement, [1989] Can. T.S. No. 2; Canada-United States Free Trade Agreement Implementation Act, S.C. 1988, c. 65.
46. North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America, [1994] Can. T.S. No. 2; North American Free Trade Agreement Implementation Act, S.C. 1993, c. 44.
47. Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, Marrakesh, 1867 U.N.T.S. 3; World Trade Organization Agreement Implementation Act, S.C. 1994, c. 47.
48. Copyright Act, supra, s. 32.
49. Copyright Act, supra, ss. 29.4 — 30.5.
50. Copyright Act, supra, ss. 30.8 — 30.9.
51. This tariff has taken a while to resolve — see case — also CDs
52. Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (26 October 1961), online: WIPO <http://www.wipo.int/treaties/ip/rome/rome-eng.html> (date accessed: 24 October 2000).
53. Statement of Royalties to be Collected for the Performance or the Communication by Telecommunication, in Canada, of Musical or Dramatico-Musical Works (Tariff 22 — Transmission of Musical Works to Subscribers Via a Telecommunications Service Not Covered Under Tariff Nos. 16 or 17), [1999] C.B.D. No. 5 [hereinafter Tariff 22].
54. Only persons who liable at law can be legally targeted for any tariff. Ibid.
55. See, supra, section .
56. Ibid.
57. Ibid.

58. It has been held that merely assisting a third party to undertake an act that that is an infringement of copyright does not constitute an authorization of that infringement. See Vigneux v. Canadian Performing Right Society [1945] 4 C.P.R. 65 (P.C.). There are also English decisions to the same effect. See CBS Inc. v. Ames Records & Tapes Ltd., [1981] 2 All E.R. 812 (Ch.); CBS Songs Ltd. v. Amstrad Consumer Electronics TLC, [1988] 2 All E.R. 383 (H.L.).
59. Copyright Act, supra, s. 3.
60. Copyright Act, supra, s. 80.
61. Statement of Royalties to be Collected for the Performance or Communication by Telecommunication, in Canada, of Musical or Dramatico-Musical Works in 1994, 1995,1996 and 1997, [1996] C.B.D. No. 9 at 27.
62. "Canadian Napster Users Are Not Freeloaders, Says in the Name of Cool Study" (10 July 2000), online: In the Name of Cool <http://www.inthenameofcool.com/2000/press-2000.html> (date accessed: 5 November 2000).
63. Included were all major Canadian broadcasters (CBC, CTV, Global, City-TV) and a number of U.S. broadcasters (NBC, ABC, PBS, WB).
64. This number grew to 17 within one month as two additional Buffalo channels, affiliates of CBS and Fox, became available.
65. The iCraveTV Web site indicated that users were required to connect to the Internet at minimum speeds of 56k, presumably to ensure reasonable transmission quality.
66. See, in general, CRTC, "Cable Television in Canada" (Jan.. 1971).
67. Canadian Admiral Corporation v. Rediffusion, Inc., [1954] Ex. C.R. 382.
68. CRTC, Policy Statement on Cable Television, "Canadian Broadcasting — A Single System" (16 July 1971) [hereinafter 1971 Policy Statement on Cable Television] at 5.
69. *Ibid.*
70. *Ibid* at 23.
71. *Capital Cities Communications Inc. v. CRTC*, [1978] 2 S.C.R. 141.
72. 1971 Policy Statement on Cable Television, *supra* note 25.
73. *Capital Cities Communications Inc. v. CRTC*, *supra* note 28 at 162.
74. Decision, CRTC 83-126, C. Gaz. 1983. I. 2490 at 2495.
75. *Canada-United States Free Trade Agreement Implementation Act*, S.C. 1988, c. 65, as amended.

76. *FWS Joint Sports Claimants v. Canada (Copyright Board)*, [1991] F.C.J. No. 501; 36 C.P.R. (3d) 483, 81 D.L.R. (4th) 412 (F.C.A.).
77. *FWS Joint Sports Claimants v. Canada (Copyright Board)* (1991), 36 C.P.R. (3d) 483 at 486 (F.C.A.).
78. *Broadcasting Act*, .S.C. 1991, c. 11, as amended [hereinafter *BA*].
79. CRTC, Telecom Public Notice CRTC 99-14, "New Media" (17 May 1999), online: CRTC ttp://www.crtc.gc.ca/INTERNET/1999/8045/03/PN99-14E.htm (date accessed: 26 August 2000).
80. J. Borland, "Net TV Keeps Streaming Despite Legal Threats" *CNET* (7 December 1999), online: CNET News.com ttp://news.cnet.com/news/0-1004-200-1484602.html?tag=st.ne.ni.rnbot.rn.1004-200-484602 (date accessed: 25 August 2000).
81. *Supra* note 20.
82. M. McCabe, "TV, Film and Online Broadcasting in the Wake of iCraveTV — What Now", online: Canadian Association of Broadcasters http://www.cab-acr.ca/english/newsroom/record/icrave_speech.html (date accessed: 25 August 2000) [hereinafter *What Now*].
83. *Tariff 22*, *supra.*
84. *What Now*, *supra.*
85. SOCAN v. Canadian Association of Internet Providers, 2001 FCA 4 (2001).

Thérèse Leroux

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La xénotransplantation : tour de force ou tour de cochon?

Résumé

Les transplantations d'organes font maintenant partie de l'arsenal thérapeutique offert au Canada. Cette pratique est même victime de son succès. En effet, elle se heurte à un obstacle de taille : les organes provenant de donneurs humains, vivants ou décédés, ne suffisent plus à répondre à une demande qui n'a cessé de croître. La xénotransplantation (la transplantation de cellules, tissus, organes vivants d'origine animale) se veut une solution à cette pénurie. Cependant, cette avenue n'est pas sans soulever de nombreux problèmes scientifiques certes, mais aussi éthiques, juridiques et sociaux. L'idée de recourir aux xénotransplantations interpelle des personnes de formation diverse. Pour un, le scientifique y voit un défi, celui de découvrir le moyen de déjouer le système immunitaire du receveur pour éviter le rejet de l'organe, phénomène ici amplifié par sa provenance. Quant à l'éthicien, l'éventualité de chimère ravive l'intérêt de s'interroger sur la spécificité de l'être humain. Face à un tel développement technologique, le juriste se veut, lui, soucieux du

respect des droits de la personne de même que sensible au sort réservé aux animaux.

La xénotransplantation se situe à un carrefour où convergent diverses problématiques visant tant la source d'organes que le receveur mais aussi la société dans sa globalité. Ainsi, en envisageant la xénotransplantation comme solution à la raréfaction des organes, on ne peut ignorer que les animaux destinés à contribuer à cet exploit auront leur patrimoine génétique modifié afin de les rendre plus compatibles avec l'organisme receveur. Alors resurgissent toutes les discussions relatives à l'expérimentation animale, aux normes visant les animaux transgéniques.

Dans le cas des receveurs, l'éventualité de la xénotransplantation suscite un important questionnement en ce qui a trait à la dignité et à l'intégrité de l'être humain, à la représentation sociale et symbolique du corps humain suite au franchissement de la barrière des espèces. Par ailleurs, comment s'assurer que le consentement requis du malade pour réaliser cette intervention est libre et éclairé? À cet égard, la nature et l'ampleur des risques associés à la xénotransplantation semblent si difficiles à identifier. En effet, des bactéries, virus, champignons peuvent être inoffensifs chez leurs hôtes naturels comme le babouin ou le porc, mais extrêmement toxiques, voire mortels chez l'être humain, d'autant que les receveurs seront soumis à un traitement immunosuppresseur. Le risque de zoonoses et l'idée que ces maladies infectieuses puissent se propager aux membres de la famille et peut-être même à la société provoquent l'éclatement de la dyade médecin-patient. Les tiers sont malgré eux partie à cette aventure. Dès lors, le consentement de l'individu devant recevoir la greffe est-il suffisant? Peut-on imaginer concilier la possibilité pour une personne de recourir à une chirurgie susceptible de prolonger sa vie et la sauvegarde de la santé publique? La xénotransplantation, comme plusieurs développements technologiques, conjugue espoirs et craintes. Compte tenu des enjeux, des valeurs et des intérêts en cause, comment la qualifier : tour de force ou tour de cochon?

Abstract

Organ transplantation, now part of Canada's therapeutic arsenal, is becoming a victim of its own success and coming up against a major hurdle: there are simply not enough organs from living or deceased human donors to meet the ever-increasing demand. Xenotransplantation -grafts of living cells, tissues and organs taken from animals — could fill the gap, though the procedure raises many scientific, as well as ethical, legal and social, considerations.

Professional perspective often influences how xenotransplantation is viewed. Scientists see it as a challenge: their mission is to circumvent the graft recipient's immune system and prevent rejection, always exacerbated when species boundaries are crossed. Ethicists, raising the spectre of the chimera (or modern-day Frankenstein), find renewed enthusiasm for pondering the specificity of human beings. And lawyers seek to ensure that human rights continue to be protected, while sparing a thought for the fate of animal donors.

Today, xenotransplantation is the focus for many convergent issues associated with organ sources and recipients, and involving society as a whole. We must acknowledge that making xenotransplantation our solution to the organ shortage would mean genetically modifying animal donors to make them more compatible with graft recipients — and that of course brings us back to the ongoing debate on animal-experimentation and standards for transgenic animals.

For graft recipients, xenotransplantation raises many questions about human dignity and integrity, and the social and symbolic representation of the human body once the boundary between species has been breached. The nature and extent of xenotransplantation-related risks have been very difficult to pinpoint, so how can we ensure that a patient's consent to the procedure would be given freely, and in full knowledge of the facts? Bacteria, viruses and fungi harmless to baboons or pigs, their natural hosts, may be highly toxic or even fatal to humans, especially since graft recipients are immunosuppressed. There is a risk of contracting infectious zoonotic diseases, spreading them to family members and even triggering epidemics; as a result, the doctor-patient relationship can no longer remain exclusive because third parties will inevitably be dragged into the equation. And once they become part of the equation, is the graft recipient's sole consent sufficient? How can we reconcile an individual's right to undergo life-saving surgery with the potential threat to public safety?

Like many other technological developments, xenotransplantation inextricably links both hope and fear. With all the issues, values and interests at stake, how are we to see it ? as a great achievement, or a can of worms?

Dans le domaine de la santé, nombreuses sont les innovations technologiques qui ont provoqué de profonds bouleversements au sein de la collectivité. Pensons aux nouvelles technologies de la reproduction, à la génétique qui ont suscité une réflexion profonde. Or, la frontière inter espèce pourrait bientôt être franchie avec l'avènement de la xénotransplantation (la transplantation de cellules, tissus, organes vivants d'origine animale à l'être humain). Cette avenue est proposée pour pallier au manque d'organes humains et pour traiter des maladies chroniques et débilitantes. Cette possibilité soulève, elle aussi, de nombreux questionnements et exige une attention toute particulière compte tenu de son originalité.

Les transplantations d'organes sont maintenant pratique courante en matière de traitement de certaines maladies[1]. Malheureusement, les organes provenant de donneurs humains, vivants ou décédés, ne suffisent pas pour répondre à une demande qui n'a cessé de croître[2]. Ainsi, le nombre de Canadiens en attente d'une greffe augmente à chaque année; il a presque doublé (93%) de 1991 à 1999, passant de 1830 à 3534 patients. La plupart d'entre eux attendent un rein (80%). Or, pendant la même période, le nombre de transplantations s'est accru d'environ 40%; en 1999, 1672 organes simples ont été transplantés alors que 60 transplantations combinées (coeur-poumon, rein-pancréas, par exemple) ont été réalisées[3]. Alors, l'idée de recourir aux animaux, en tant que "donneurs", pour pallier à cette pénurie chronique d'organes a refait surface[4]. En effet, la réalité de la xénotransplantation avait déjà été portée à la connaissance du public il y a une quinzaine d'années de façon particulièrement dramatique avec le cas de "Baby Fae", un nouveau-né de sexe féminin qui reçut le coeur d'un babouin lors d'une opération effectuée le 26 octobre 1984 au Loma Linda Medical Center en Californie. Le bébé était âgé d'à peine quinze jours et survécut encore vingt jours après la transplantation[5].

Bien que cette "percée" ait été sans lendemains immédiats, la technologie des xénogreffes a fait depuis des progrès considérables. Une meilleure maîtrise des phénomènes de rejet que ce soit par l'utilisation de médicaments immunosuppresseurs améliorés, chez les receveurs, ou grâce à certaines modifications du patrimoine génétique des animaux-donneurs, dont les organes deviennent par là davantage

compatibles avec l'organisme des receveurs fait miroiter un avenir prometteur pour la transplantation interespèce[6]. D'ailleurs, des cellules foetales de porc ont déjà été transplantées chez des patients pour ralentir la progression de la maladie de Parkinson et celle d'Huntington ou encore traiter l'épilepsie[7].

L'éventualité d'un traitement par xénotransplantation était devenue à ce point sérieuse et imminente qu'aux États-Unis, l'Institut de médecine (IOM) de l'Académie Nationale des Sciences a mis sur pied un comité spécialement chargé d'étudier les problèmes qui se posent dans le domaine des xénogreffes : protection des personnes qui serviront de sujets "pionniers", risques de transmission d'agents pathogènes de l'animal aux populations humaines et impact psychologique sur le public[8]. D'autres pays ont également réagi, dont le Royaume-Uni[9], la Suisse[10], les Pays-Bas[11], l'Espagne[12], la Suède[13], et même l'Organisation mondiale de la santé[14]. Le Canada a lui aussi amorcé une réflexion sur ce sujet. Ainsi, sur recommandation du Groupe d'étude d'experts sur la sécurité des organes et des tissus, Santé Canada a organisé, en novembre 1997, un Forum national sur la xénotransplantation[15]. Plus récemment, Santé Canada a annoncé son intention d'élaborer un cadre réglementaire au sujet des xénogreffes[16]. En septembre 1999, le Programme des produits thérapeutiques de Santé Canada diffusait pour commentaires l'ébauche de la *Proposition d'une norme canadienne pour la xénotransplantation*[17]. Enfin, le 10 août dernier, le ministre de la Santé, monsieur Allan Rock, annonçait le lancement d'une consultation publique sur la xénotransplantation, confiée à l'Association canadienne de santé publique.

L'idée de recourir aux xénotransplantations interpelle des personnes de formation diverse. Pour un, le scientifique y voit tout d'abord un défi, celui de découvrir le moyen de déjouer le système immunitaire du receveur pour éviter le rejet de l'organe, phénomène ici amplifié par sa provenance; mais éventuellement une difficulté, celle d'identifier et de contrôler les agents pathogènes susceptibles d'être transmis lors de la greffe. Quant à l'éthicien, l'éventualité de chimère ravive l'intérêt de s'interroger sur l'identité profonde de l'être humain. Face à un tel développement technologique, le juriste se veut quant à lui soucieux du respect et de la sauvegarde de la dignité humaine et des

droits de la personne et critique du rôle de l'État comme agent de régulation. La xénotransplantation se situe à un carrefour où convergent diverses problématiques visant tant l'animal pourvoyeur d'organes que le receveur mais aussi la société dans sa globalité.

A — Controverses

Pour les fins de cet exposé, nous examinerons certaines controverses qui mettent en cause trois acteurs impliqués dans la réalisation de la xénotransplantation : (1) l'animal-pourvoyeur, (2) le patient-receveur et (3) la société-spectateur. Pour chacun, nous présenterons très sommairement deux points qui suscitent des discussions et alimentent la réflexion.

1 — L'animal-pourvoyeur

Pour favoriser les chances de succès de cette nouvelle intervention chirurgicale, les chercheurs ont tout d'abord dû sélectionner l'espèce animale devant fournir les organes, tissus et cellules. Ensuite, pour parer les phénomènes de rejet qui surviennent peu après l'implantation dans le corps humain d'un organe d'origine animale, ils ont décidé de modifier la structure génétique de l'organe, en créant des animaux transgéniques. Cette altération du patrimoine génétique de l'animal n'est pas sans soulever des interrogations.

- *Le choix de l'espèce*

Les premières tentatives de xénotransplantation qui se sont toutes soldées par des échecs ont impliqué des organes prélevés chez des porcs, des chèvres, des primates[18]. Mais parmi ces espèces susceptibles de se transformer en réservoir d'organes, de tissus et de cellules, le porc a été désigné le pourvoyeur puisque le mieux adapté pour jouer ce rôle. Il a délogé les primates initialement considérés comme les meilleurs "donneurs" potentiels. D'un point de vue fonctionnel mais aussi sous l'angle de la dimension, il apparaît que les organes de porc sont plus appropriés pour ce genre d'intervention que les organes provenant de primates supérieurs, tels les chimpanzés ou les babouins, pourtant génétiquement bien plus proches de l'homme[19]. Le haut degré d'intelligence et de sociabilité des primates, le fait que certaines espèces soient

en voie de disparition de même que le nombre restreint de petits et le temps requis pour leur croissance sont d'autres facteurs qui font obstacle à leur élevage pour fins de prélèvement d'organes[20].

• *Le transgénisme animal*

En envisageant la xénotransplantation comme solution à la raréfaction des organes, on ne peut ignorer que les animaux destinés à contribuer à cet exploit seront fort probablement modifiés génétiquement[21]. En effet, grâce au génie génétique impliquant notamment l'introduction de gène humain chez le porc, on cherche à modifier la structure génétique de l'organe implanté de façon à diminuer le rejet suraigu de greffon[22]. Par exemple, selon Vanderpool, une compagnie en biotechnologie aurait transplanté des organes de porcs transgéniques chez des primates non-humains et aurait réussi à obtenir un taux de rejet inférieur à 2%[23]. Alors resurgissent toutes les discussions relatives à l'expérimentation animale, aux règles de protection des animaux, aux normes plus spécifiques devant s'appliquer aux animaux transgéniques. Cette nouvelle utilisation des animaux influencera-t-elle nos relations avec ces derniers, qui sont marquées par l'anthropocentrisme? Quel est le poids du bien-être animal vis-à-vis du bien-être humain? S'agit-il d'un prolongement inévitable de notre emprise sur le sort réservé aux animaux, d'une nouvelle forme de domestication pour répondre à nos besoins vitaux? Comment concilier ce nouvel usage avec les courants de plus en plus présents[24] qui revendiquent un statut moral pour l'animal voire des droits?

2 — Le patient-receveur

Entre autres, parce que la xénotransplantation peut être vue comme l'ultime ressource pour éviter une mort certaine, la sélection du receveur mais également le processus de prise de décision de ce dernier méritent notre attention.

• *Le consentement libre et éclairé*

Quant aux receveurs, la xénotransplantation provoque un important questionnement en ce qui a trait à la dignité et à l'intégrité de l'être humain, au consentement requis pour réaliser cette intervention[25].

Comment en effet s'assurer qu'il s'agit bel et bien d'un consentement qui soit libre et éclairé? Pour que les receveurs puissent prendre une décision informée, ils doivent pouvoir connaître les risques; mais est-ce possible compte tenu des données scientifiques actuellement disponibles? La nature des risques associés à la xénotransplantation semble si difficile à identifier[26].

Les risques médicaux proviennent principalement de problèmes reliés au rejet du greffon et aux infections. La barrière immunologique doit être déjouée pour permettre à l'organisme humain de reconnaître ou tenir pour sien l'organe transplanté. Mais ce faisant, plus l'immunosuppression est forte, plus la susceptibilité à l'infection augmente[27]. Or, divers agents peuvent être à l'origine des infections zoonotiques : rétrovirus, virus endogènes, prions, ...[28]. Les scientifiques reconnaissent que des bactéries, virus, champignons peuvent être inoffensifs chez leurs hôtes naturels comme le babouin ou le porc, mais extrêmement toxiques, voire mortels chez l'être humain[29], d'autant que les receveurs seront soumis à une immunosuppression plus importante que dans le cas d'une allogreffe[30]. Même des animaux sains peuvent transmettre des rétrovirus endogènes lors de la transplantation, qui peuvent être nuisibles pour les humains[31]. Par exemple, deux rétrovirus endogènes porcins (PERVs), capables d'infecter et de se répliquer *in vitro* dans des cellules humaines, ont été découverts dans des laboratoires en Grande-Bretagne[32]. Par ailleurs, des prions seraient probablement les agents dans la transmission de l'encéphalopathie bovine spongiforme (la maladie de la vache folle). Le greffe d'un organe d'une espèce à une autre constitue donc une situation aux conséquences difficilement prévisibles.

- *L'allocation des ressources*

À certains égards, la xénotransplantation loin de résoudre les problèmes associés à la pénurie d'organes, les accentue ou les modifie. Ainsi, au dilemme déjà existant du choix du bénéficiaire de la greffe[33], s'ajoutera la décision tout aussi troublante quant à l'origine de l'organe offert, animal ou humain. Qui recevra un organe humain? À qui sera attribué un organe animal? Quels critères permettront de faire ce choix sans créer une hiérarchisation des receveurs. Est-on plus favorisé lorsqu'on

reçoit un coeur neuf de porc transgénique ou lorsqu'on nous transplante un coeur usagé d'origine humaine? Au-delà des risques associés à la technique chirurgicale en tant que telle, de la qualité du produit transplanté, la protection de la dignité humaine milite-t-elle en faveur d'organes homologues plutôt qu'hétérologues. Le droit à l'intégrité de la personne, droit fondamental par excellence, implique-t-il que la préséance doit être accordée aux organes d'origine humaine?

3 — La société-spectateur

Face à cette percée technologique, la société semble un partenaire captif. Jusqu'à ce jour, elle a été plutôt silencieuse. Pourtant, les risques associés à cette intervention ne se limiteront pas nécessairement au greffé mais peuvent se propager en son sein. De plus, les conséquences qu'engendrera l'acceptation de cette technique dans l'arsenal thérapeutique, dont les coûts, ne devraient pas la laisser indifférente.

- *La protection de la santé publique*

La possibilité d'une contamination inédite par l'organe provenant d'un animal transgénique exige une attention particulière. La préoccupation de protéger les receveurs mais également la collectivité[34] est d'autant plus vive suite aux incidents malheureux reliés aux cas de transmission de la maladie de la vache folle[35] et à l'existence de rétrovirus endogènes chez les "donneurs" éventuels comme le porc[36]. Le virus de l'immunodéficience acquise chez l'humain (VIH), un rétrovirus, est un exemple du passage d'un agent infectieux de l'animal à l'homme. Les chercheurs croient en effet que la pandémie du SIDA provient de souches simiesques. Le virus Ebola viendrait lui aussi de mammifères. Le virus de la grippe qui a tué 20 millions de personnes dans le monde en 1918 était issu d'une source porcine[37].

Qu'il s'agisse de greffe permanente ou de transition, la possibilité d'affecter la santé publique demeure. Même un usage temporaire de l'organe vivant animal soulève un problème au niveau de la transmission de virus de l'animal à l'être humain. En effet, il est possible que la période pendant laquelle le patient survit grâce à l'organe animal ait en fait servi de période d'incubation pour des agents infectieux qui auront trouvé un hôte pour se propager aux proches,

voire à la population[38]. Bien que l'organe animal soit enlevé pour faire place à un organe d'origine humaine, que le patient en ait bénéficié pour pallier à un manque d'organe compatible, le mal peut être fait ... Le risque est non quantifiable, peut-être peu probable mais ses conséquences potentielles, si désastreuses, exigent de ne pas l'ignorer. La protection de la santé publique devrait donc être omniprésente dans l'élaboration des normes devant régir la sécurité d'une technologie innovatrice. Cette attention est d'autant plus cruciale lorsqu'il s'agit d'un développement sans précédent dans l'histoire de l'humanité. En effet, la xénotransplantation ne recourt pas à une prothèse usuelle en matériau inerte ou un organe d'origine humaine mais implique plutôt l'incorporation possiblement permanente, intime d'un organe, de cellules, de tissus vivants d'une espèce étrangère.

- *La prise en charge des coûts*

Par ailleurs, il est plausible d'affirmer que les tiers seront malgré eux partie à cette intervention en tant que payeurs d'impôts pour financer les coûts afférents à cette chirurgie. Avec une source quasi illimitée d'organes et de tissus, combien de xénotransplantations sera-t-il possible d'effectuer? Il est sans doute vraisemblable de prétendre que compte tenu de l'accessibilité accrue des organes et tissus, les critères de sélection des personnes pouvant bénéficier d'une greffe seront élargis, ce qui augmentera le nombre d'interventions chirurgicales proposées. Or, les organes, tissus ou cellules n'étant plus d'origine humaine, il faudra les payer. En effet, les animaux, même transgéniques, demeurent des choses et peuvent donc faire l'objet de transactions commerciales. D'ailleurs, les compagnies qui investissent présentement pour développer cette avenue thérapeutique voudront sûrement récupérer les dépenses de recherche. Dans ces circonstances, notre système de santé saura-t-il absorber les coûts associés à cette percée technologique et dès lors, répondre à la demande?

B — Contrecoups

Avant de poser un jugement final sur l'acceptabilité de cette innovation technologique, il est certes opportun d'imaginer quelles pourraient être certaines conséquences de son développement. Pour les fins de la

discussion, limitons-nous à trois éléments. Tout d'abord, le fait de recourir à des animaux pour pallier à la pénurie chronique d'organes pourrait mettre en péril nos repères identitaires. Cette relation des plus intime, soit la transplantation d'organe, de tissu vivant d'origine animale à l'être humain, peut sans aucun doute accentuer le flou entre les espèces; d'autant que la frontière entre l'humain et l'inhumain est aussi menacée par d'autres développements scientifiques. En outre, le fait de préconiser la xénogreffe plutôt que l'allogreffe pourrait mettre en péril une composante majeure du don d'organes : la solidarité humaine. En effet, dans l'état actuel, la personne qui accepte qu'on prélève des organes à son décès, le fait par esprit de partage, l'essence même du don. Enfin, la xénotransplantation pourrait mettre en péril le principe de l'autonomie, pourtant reconnu au patient receveur. En effet, par souci de limiter les atteintes à la santé publique, le receveur doit s'engager à respecter des conditions de suivi très strictes transformant alors le consentement à l'expérimentation ou aux soins en véritable contrat d'adhésion.

1 — Mise en péril des repères identitaires

La xénotransplantation, comme plusieurs développements scientifiques, peut avoir des répercussions sur nos représentations quant à l'identité humaine et à celle du corps. À l'aube du nouveau millénaire, la question ultime demeure : Qu'est-ce que l'être humain? Qu'est-ce qui le caractérise? L'être humain n'est-il qu'une autre forme de vivant? La xénotransplantation provoquera-t-elle une dérive identitaire due à la promiscuité qui en résulte? L'effacement progressif de la barrière entre l'espèce animale et l'espèce humaine peut s'observer tant lors de la création d'animaux transgéniques (gènes humains chez l'animal) que lors de l'incorporation de l'organe animal chez le patient. L'éventualité de cette percée technologique redessine la frontière de l'identité humaine et amène donc à revisiter des concepts fondamentaux comme la dignité humaine, l'intégrité de la personne et la pertinence de la distinction fondatrice (juridique et religieuse) en Occident entre l'animal et l'être humain.

2 — Mise en péril de la solidarité humaine

Certains craignent que la publicité accordée aux exploits chirurgicaux comme la xénotransplantantion n'amène les gens à croire qu'enfin le problème chronique de pénurie d'organes est résolu, alors que nous serons toujours à l'étape expérimentale et que le besoin d'organes sera toujours criant. La perspective que la production industrielle d'animaux transgéniques saura supplanter l'utilisation d'organes humains incitera peut-être des personnes à négliger de signer la carte attestant leur souhait de donner leurs organes. La solidarité humaine qui sous-tend cette décision personnelle de donner, de partager avec autrui dans le besoin, en l'occurrence besoin d'organes, pourrait être mise à rudes épreuves. Ce phénomène de ressac est d'autant plus prévisible que nombreuses sont les personnes qui sont actuellement réticentes à manifester à leur entourage leur décision de donner leurs organes, lors de leur décès.

3 — Mise en péril de l'autonomie de la personne

La crainte d'une contamination inédite par l'organe provenant d'un animal transgénique semble être à l'origine des mesures exceptionnelles envisagées quant au suivi des receveurs[39]. Ainsi, l'éventuel receveur devra s'engager à respecter les contraintes d'un contrôle épidémiologique rigoureux pour le reste de ses jours. Certains envisagent même la possibilité de quarantaine pour limiter les déplacements et la propagation d'éventuels agents infectieux. Comme les risques peuvent se manifester pas uniquement au moment de la chirurgie mais sur une période plus ou moins longue, il devient nécessaire de prévoir la mise sur pied d'un registre pour répertorier le suivi des personnes transplantées[40]. En plus, le receveur devra consentir que des prélèvements de tissus soient effectués et conservés dans une banque centrale. Il devra également autoriser une autopsie à son décès.

La présence de ces exigences dans le formulaire de consentement, malgré l'objectif louable qu'elles poursuivent soit la protection de la santé publique, semble mettre en échec un principe pourtant reconnu en expérimentation chez l'humain. Tant la *Déclaration d'Helsinki*[41], l'*Énoncé de politique des trois Conseils*[42] que le *Code civil du Québec*[43] énoncent le droit de retrait pour le participant à une

expérimentation. Est-ce que la xénotransplantation est à ce point exceptionnelle qu'elle transforme le consentement à l'expérimentation en un contrat d'adhésion? L'autonomie de la personne, son inviolabilité, le respect de sa vie privée ne sont-ils pas menacés?

Conclusion

La greffe d'un organe d'une espèce à une autre constitue une situation aux conséquences difficilement prévisibles. Les zoonoses créent des risques non seulement pour le receveur d'organe mais aussi pour ses proches, l'équipe médicale et le public en général. Comment peut-on alors concilier la promotion du bien-être d'un individu avec la sauvegarde de la santé publique?

Une décision collective devra être prise quant au niveau de risque qui serait raisonnablement acceptable dans les circonstances en regard des intérêts en cause. Conscient que le seuil tend de plus en plus vers la tolérance zéro, Santé Canada a jugé essentiel de consulter le public avant d'autoriser les xénotransplantations expérimentales. Nous sommes tous interpellés par ce développement scientifique, il est donc crucial de faire connaître notre point de vue. À cet égard, je vous invite à consulter le site internet géré par l'Association canadienne de santé publique dont l'un des objectifs est justement de recueillir votre opinion sur cette percée technologique.

La xénotransplantation, comme plusieurs développements scientifiques, conjugue espoirs et craintes. Compte tenu des enjeux, des valeurs et des intérêts en cause, comment la qualifier : tour de force ou tour de cochon?

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the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed." (nos soulignements)

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43. L'article 24 énonce : "**Le consentement** aux soins qui ne sont pas requis par l'état de santé, à l'aliénation d'une partie du corps ou **à une expérimentation** doit être donné par écrit. Il **peut toujours être révoqué, même verbalement**

Colleen Clements

Colleen Clements

British Beef, Ontario Water and Dead Crows

Abstract

By definition, a public policy mistake is a large one because such decisions are made on the population level. This article identifies seven ethical concepts crucial to public and health policy, showing through current public health examples that these concepts may help avoid such major mistakes.

Past experience with HIV public policy on a national and global level indicates the urgency of ethical analysis. Current major policy issues include the exploding problem of transmissible spongiform encephalopathies (TSEs) popularly known as Mad Cow Disease which are spreading across Europe and generating both health and political/foreign policy concerns as indicated by a 12/26/2000 report on the American Broadcasting Company's "Nightline." Another issue is the resurging virulence of E. coli 0157:H7 which can be found in meat, water, some fruits and vegetables, and in a communicable form in day care centres. Finally, this article looks at the inadequate and failed attempt to prevent West Nile Virus from becoming established on the North American continent, where public policy and public relations became confused.

The seven ethical concepts which are discussed are: conflicts of interest; how and where on the Don't Panic Scenario vs. Doomsday Scenario to place the problem; informing and involving the public vs. causing harm by premature or unjustified precautionary actions; expert standards of objective, critical thinking/expert obligation; risk assessment and risk/benefit analysis; uncertainty in ethics; balance in a natural system.

This analysis concludes that postmodern bioethics (which is highly politicized) needs to be replaced with a systems bioethics and adherence to the scientific standards of the enlightenment.

Résumé

Par définition, toute erreur de politique publique est grave dès lors que ces décisions s'appliquent à l'ensemble d'une population. Cet article expose sept notions d'éthique fondamentales pour toute politique publique et démontre, par des exemples actuels de la politique en matière de santé, que leur application pourrait permettre d'éviter ce genre d'erreurs graves.

La politique publique concernant le VIH nous a révélé, sur le plan national aussi bien que planétaire, qu'il est urgent d'adopter le principe de l'analyse éthique. Au nombre des grands dossiers de politique actuels figure le problème explosif des encéphalopathies spongiformes transmissibles (EST), mieux connues sous le nom de maladie de la vache folle, qui sont en train de se propager dans toute l'Europe et représentent une préoccupation de premier ordre qui inquiète à la fois les milieux de la santé, les pouvoirs publics et le monde de la politique étrangère, comme en atteste un reportage diffusé le 26 décembre 2000 à l'émission *Nightline* du réseau américain ABC. Un autre de ces grands dossiers est le regain de virulence du bacille E. coli 0157:H7 qui peut être présent dans la viande, dans l'eau, dans certains fruits et légumes, mais aussi, sous une forme transmissible, dans les garderies. Enfin, cet article expose la tentative insuffisante et infructueuse qui a été faite pour empêcher le virus du Nil occidental de prendre pied sur le continent nord-américain, une tentative marquée par une politique publique et des relations publiques de plus en plus confuses.

Les sept notions d'éthique exposées par cet article sont les suivantes: les conflits d'intérêts; comment et où situer le problème entre les deux scénarios extrêmes "Pas de panique" et "L'apocalypse"; informer et faire participer le public par opposition à prendre des mesures de précaution prématurées et injustifiées, et donc préjudiciables; les normes expertes du raisonnement objectif et critique par rapport aux obligations expertes; l'évaluation du risque

et l'analyse comparative des risques et des avantages; l'incertitude en éthique; et l'équilibre dans un système naturel.

Cette analyse conclut que la bio-éthique postmoderne (qui est hyper-politisée) doit être remplacée par une bio-éthique des systèmes et par le respect des normes scientifiques du savoir éclairé.

Ethics, Public Policy, and Infectious Disease in Three Current Cases

When a public policy mistake is made, by definition it is a large one because of the population numbers involved. I am going to identify 7 ethical concepts that are crucial to public and health policy, and suggest that working with these concepts may help in avoiding some of the more obvious mistakes.

1. *Conflicts of Interest.* Because different levels of a natural system have varying characteristics, needs and interests, it is usual, not unusual, that policy making will likely contain embedded conflicts among these levels. Conflicts involving what is included in the community to which the expert has an ethical obligation are common. The standard I use in identifying this ethical community is based on a humanistic theory of the base of ethics: "It's a wise species that knows what its self-interest is." Within that human ethical community there are also conflicts, and again from a naturalistic understanding of the human organism, the standard that makes most theoretical sense to me is: "Love begins at home." This identification of whose interests comprise the ethical obligation of a policy expert are thorny enough, but we also need to add the conflicts brought to the table by the policy makers themselves, whose legitimate role descriptions are often in conflict. Consider the AIDS/HIV screening of blood donors issue. Operators of blood banks, infectious disease experts from the Centers for Disease Control, civil rights activists, and patients who need a blood transfusion all have natural and different perceptions of the risks involved in screening or not screening blood donors for a lethal disease. The Ebola virus is another example of conflicts of interest inherent in the natural situation. Virologists who need to fund their research labs, government managers trying to limit resources to the medical field, environmentalists who wish to criticize human intervention in the tropical forests, developing countries who need assistance with outbreaks, and North American citizens who are singularly focused on health — all are funneled through governmental hearings that attempt to make policy recommendations on a recently discovered filovirus that has never been able to move from outbreak to epidemic.

Self-awareness of conflicts of interest on the part of policy makers is an ethical requirement, as is making clear to others involved how the particular expert role already presumes certain interests over others. This initial assessment of conflicting roles is as important as a risk assessment for policy planning. I want to try and discuss each of these 7 ethical concepts, but for now, let me list them and then look at 3 case examples that may help in developing the importance of ethics for public policy.

2. *How and Where on the Don't Panic Scenario vs. Doomsday Scenario to Place the Problem.*
3. *Informing and Involving the Public vs. Causing Harm by Premature or Unjustified Precautionary Actions.*
4. *Expert Standards of Objective, Critical Thinking/Expert Obligation.*
5. *Risk Assessment and Risk/Benefit Analysis.*
6. *Uncertainty in Ethics.*
7. *Balance in a Natural System.*[1]

The Ethical Mistakes in Mad Cow/Transmissable Spongiform Encephalopathies and What We Can Learn From Them

We should already have learned the human costs of health policy mistakes following our almost 20 year experience with the ethical mistakes made in AIDS/HIV policy. Optimistically, I could conclude that we have partly learned, but pessimistically, I could conclude, not much. Major ethical risk/benefit errors were unnecessarily made in policy decisions about screening blood donors, implementing testing, premature consensus, identifying risk groups, deceiving the public about spread in the general population for funding purposes, and using standard public health measures such as closing bath houses [2, 3]. That list was only for North America. For Africa, the list would have been longer. The results of this hardened policy consensus still haunt us. The French Association of Hemophiliacs estimated that in 1991 1,200 of 3,500 hemophiliacs were positive for HIV. In the US, 12,000 individuals became infected with HIV before testing was instituted or screening begun or the problem even acknowledged to the public, and 70% of all

US hemophiliacs during that period became infected with HIV. In Africa, AIDS/HIV has simmered across the center of the continent to the West coast, South Africa, and East Africa, with countries previously not having more than sporadic cases now experiencing (if the testing is accurate) epidemics, e.g., Ethiopia. My daughter's sister-in-law is an epidemiologist now working on preventive education in her native country of Ethiopia, where this disease has spread significantly, but that very policy of focusing primarily on preventive education may be a policy mistake of large proportion [4]

After that lesson, it would seem that health policy made for bovine spongiform encephalopathy (BSE) would have benefited and avoided the most apparent mistakes. But in 1999, the arguments over screening blood donors to prevent the variant Creutzfeldt-Jakob (vCJD) disease transmitted from beef to humans seem to repeat the same pattern.

In my ethics columns for *The Medical Post*, I had found calling this progressive neurological disease (probably caused by a misfolded protein) SE (spongiform encephalopathy), properly reflected that the SEs cross species easily through a variety of transmissions and manifest themselves in modified clinical signs depending on the species. This would avoid the confusion of Yellow Fat disease for mink, scrapie for sheep, Mad Cow for cattle, kuru and CJD for humans, chronic wasting disease in deer and elk, and whatever it will be named in ostriches. The scientific literature is now calling this infectious disease grouping TSEs, and this name will help clarify policy and clear up public understanding.

I have been intrigued with TSEs since I first heard Carleton Gajdusek's presentation at our medical school some 15 years ago. When we conducted our AIDS Training Project, we discussed CJD and its iatrogenic transmission through organ transplants, human growth hormone injections, surgical instruments, and most likely, blood. Because of this interest, I followed the outbreak of BSE and vCJD in Great Britain very closely, picking up the first public reports in 1986. I also watched the repeating public policy ethical mistakes.

In the beginning of the outbreak and the epidemic in cattle herds that followed, policy officials inaccurately reassured the (deceived) public. The media characterized BSE as specific only to cattle. Blue-

ribbon committee reports were kept secret and only became public when a committee member faxed a list of human cases of vCJD to the wrong fax number. Blood and other organ banks resisted any possibility that it could be transmitted through blood or other donations, and experts kept talking about the lack of proof (no documented case) of cattle-to-human transmission. This public misinformation was done despite accessible veterinary information that the SEs had in the past spread from sheep to mink, and that the likely infection to cattle came from sheep with scrapie. It was done despite Dr. Gajducek's award-winning work on the spread of an SE, kuru, from human to human, most likely through ritual funeral cannibalism among the Fore of New Guinea. It was done despite pediatric evidence that human growth hormone batches (3 worldwide) had infected treated children with CJD. Finally, government health and agricultural policy makers fought to save the British beef industry, still are fighting, with the same fervour that San Francisco health and public officials had fought to save the gay bath houses in the early days of AIDS/HIV.

However, a policy choice was made about screening blood donors for TSEs fairly early in the history of this new outbreak of a lethal infectious disease (1999), with North American blood banks screening out donors who spent six months or more in the UK between 1980 and the present. In the absence of a reliable blood test, screening is the best that can currently be done.Research on sheep has documented that TSE can be transmitted through the blood supply. Again, the experts attempted to maintain a Don't Panic scenario, because for Great Britain this means that the blood supply is likely contaminated with TSE and cannot be seen as safe, yet blood transfusions will still have to be used in medical care. What further complicates the response to TSEs are the political and economic factors in public policy decision that were also prevalent in AIDS/HIV, and the relatively easy way that policy can become so politicized within a specific ideological consensus that even science becomes affected. I have just completed a book that argues, in fact, that current postmodern bioethics has politicized medicine and bioscience within an ideological consensus to the detriment of patients, professionals, the epistemology of science, and the rationality of philosophic ethics [5].

A key ethical concept is conflict of interest. In this case, the response of experts with a potential conflict of interest because of involvement with blood banks mimicked the response of 18 years ago. Some experts still question the transmission of vCJD/TSE from eating beef, although that question has long ago been answered or, given the history of scrapie (the TSE in sheep), never should have been asked in the first place. To suggest to the public that there is no inferential evidence of transmission between cattle and humans deliberately overlooks the long history of TSEs and their inter-species transmission through injestion, the adequate evidence that TSEs appear inter-species transmissable no matter what the species, and the now solid scientific evidence after the British outbreak of transmission to humans, lemurs, cats, and ostriches[6]. As was the case for human growth hormone contaminated with the CJD agent, it takes time for monkeys or chimps to develop the symptoms of TSE after injection, since this is a "slow" pathogen, taking as long as 20 years to produce signs. Public health agencies did not wait for unnecessary absolute proof (a documented case where the chain of transmission is as formally-established as the defense attorneys for OJ Simpson would demand). All 3 world batches of HGH were removed from the market and in making that sound inferential judgment, policy makers avoided for pediatric patients what may lie ahead for the British population. If TSE can be transmitted by organ donation, growth hormone injection, and cuts in the gloves of neurosurgeons, it is an adequately established risk for the blood supply, and the various role obligations of policy makers to their systems or constituencies which can lead to conflicting interests need to be put on the table. That policy on the blood supply was just scientifically confirmed by an article in *The Lancet* reported in the *New York Times* [7]. Blood banks, agricultural and marketing ministries, global free trade organizations, managers of laboratory resources, infectious diseases centers have an ethical obligation that overrides their role obligation, and that is to identify and correct for their role conflicts of interest.

Their role interests may partly determine whether they view the policy issue closer to a Don't Panic Scenario or a Doomsday Scenario. With confusing public information, and with withholding of some information, the consensus presentation of BSE has tended toward the

Don't Panic Scenario. When the US government planned to seize and destroy 400 sheep in Vermont because of lab evidence of either scrapie or BSE, the owners objected that BSE had not been shown to infect sheep, except in the laboratory. This only means a specific transmission has not been documented in the natural setting, but in fact the lab finding was sufficient. Still, the New York Times story said that agricultural experts chose to err on the side of caution, when the evidence was sufficient to say no error had occured in identifying the risk. The spokesman for the Department of Agriculture called the seizures acting with "an abundance of caution," but this is not an abundance. Rather, it is normal, sensible caution based on adequate data. Given such a choice for Don't Panic, it was easy for the sheep owners to call the seizure "Gestapo tactics" that were based on "questionable" science, when in fact nothing was further from the truth[8].

But we should not blame the public. The owner who wanted seizures delayed until determination of whether the sheep really had TSE was not educated to know that scrapie *is* a TSE. The news story also did not bother to educate the public that the 180,000 cattle infected with BSE were infected through feed that included the rendered brains of "diseased" animals, not bothering to mention the animals were sheep dead from scrapie[9]. When a senior staff veterinarian of the Department of Agriculture is quoted as saying that scrapie has appeared in sheep for centuries but not affected humans, the public does not know how much of a misrepresentation that is. For an owner to say there "has never been a sheep in the whole world that has gotten mad cow disease" is to show how misinformed the public has been and how deceptive the Don't Panic choice of policy may be[10]. Other evidence is available to make a policy choice of the Don't Panic Scenario unethical.

In French zoos, all 18 apparently healthy lemurs were infected with BSE, probably as a result of feed manufacturers adding British beef until 1996, much too late a date given what the experts knew. In France, BSE is spreading, requiring cattle herds be destroyed, and it is found in native-born cattle in 10 European countries. Again, a bit late, policy makers have responded by moving further toward the Doomsday Scenario on the continuum. France is random testing all cattle who died exhibiting suspicious behavior. The European Union is urging broader

preventive measures by its 15 members. France is refusing shipments of British beef, which has touched off a legal trade battle with the EU which is still insisting on a policy that British beef is as safe as any, so both policies are occupying opposing territory on the continuum. The US policy agrees with France on the risk, banning British beef. The US has a homegrown problem in its wildlife in several western states (calling the TSE chronic wasting disease). In one county in Colorado, 15% of deer are infected, and elk throughout the west have TSE[11]. In August of 2000, Spain made its policy move, destroying 2,400 sheep after detecting its first case of scrapie, and planning to destroy another 400. In the continuing confusion of public relations and policy, this news report stated that experts now knew BSE (Mad Cow Disease) did jump species barriers. Well, yes[12].

This confusion illustrates the ethical tension between informing and involving the public, and concern about causing more harm by premature or unjustified precautionary actions. Such a policy is difficult enough to make ethically and scientifically, even when the experts are operating on standards of objective, rational thinking, corrected for bias and conflict of interest, open to new experiences and data, and honest with informing the public rather than using public relations to deceive. When the policy institutions are politicized and responsive to ideological agendas and power strategies (e.g. AIDS/HIV, the TSEs, Ebola virus, West Nile virus), public policy in infectious diseases may ethically fail the human population.

Questions about BSE policy are frequent when we consider risk assessment and risk/benefit analysis. Projections for British vCJD deaths range from a few dozen to several thousand or hundred thousand, an indication of uncertainty that is very high. Reported deaths have so far ranged from more than 35, about 50, to 59 if 2 deaths in France and 1 in Ireland are counted, to the most recent, 82 in Britain. The initial policy choice about these figures in the early days, when they were first in the teens, was to avoid really involving the public and keeping information restricted (but the mistaken fax number ended that policy). The changed policy makes mortality numbers slowly available and also reports on possible trends. The recent deaths of 14 with 5 others dying (as many as had died all the previous year) suggests to

some experts that an epidemic is in the early stages. One expert estimate is that such a trend, if it continued (remember a risk assessment mistake; no trend should be projected indefinitely), could result in 500,000 deaths over the next 30 years. Some experts give a range, even if the numbers fall, of between hundreds and thousands of deaths. The most conservative position on projections comes from the acting director of the Spongiform Encephalopathy Advisory Committee which advises the British Government. Dr. Peter Smith is not ready to make a projection based on the new numbers, but did give out new numbers on deaths currently: 74 in Britain, 2 in France, 1 in Ireland (already underreported). He found the increase in deaths in 2000 to be surprising but not necessarily meaning a large epidemic[13]. So we are still left with projections all over the board such as 75 people dying in the next 20 years (that one has to be wrong) through 80,000[14]. It is easy to see that risk assessment and risk/benefit analysis will be difficult for policy planners at best.

The exposure of the British public was high, but that is only one factor. The infectivity of TSEs is not sufficiently known, The length of time before symptoms gives the pathogen the advantage in trying to contain an epidemic, until a test can be developed. But policy must be made, even with such uncertainty, and the stakes are high. The history of the spread of a TSE in the Fore people is field evidence that can reasonably be used. Our knowledge of the speed of blood transmission of HIV is also valuable. Setting aside the ideological consensus of bioethics (European colonial discrimination, civil rights expansion for homosexuals, cost-containment, global economy), policy makers can work with inferentially-known probability figures. That statistical component is only one of the components of risk. The Risk Equation is: (1) the statistical, probability risk, (2) the severity of the consequences of taking the risk, (3) the individual's control of choice to take the risk or the imposition of the risk without individual control[15, 16]. We already know that the severity is the highest possible in many senses: invariably fatal, untreatable disease that progessively takes away the important human function of thinking, perceiving, interacting, and consciously-being. Without the first step of donor screening, we also know the individual has no choice about taking the risk except to refuse life-saving

blood transfusions. This adds up to a very high risk perception for any rational being, and it is a somewhat preventable risk.

Other experts, making a risk/benefit or cost/benefit analysis in a utilitarian sense, want to argue that the focus should be on more common blood pathogens before investing the staff, time, and economic resources on TSEs. This is a divide-and-conquer approach that has no logical merit, unless economic first-order decisions can be justified, and these decisions are not even on the table for discussion[17]. From a full and scientific risk/benefit analysis, the 3% loss in blood donations is an ethically acceptable price, and the writing is on the wall that blood transfusion is a biohazard that needs an alternative. This may be an even easier ethical policy decision to make if the misfolded protein of Alzheimer's disease, found to be very similar to the misfolded protein of the TSEs, is also considered as a potential blood-borne pathogen.

The ethical concept of balance, based on natural systems, can help make the BSE policy. Deaths ranging from 80,00-500,000 have a sufficient impact on the individual level of the natural system to require some intervention at the economic level of ministries of argiculture and marketing and free trade associations, or those levels may find serious internal repercussions that threaten function and controlled-state.

The Ethical Mistakes in E. coli Contamination of Municipal Water in Walkerton and What We Can Learn From Them

The coin of the realm for experts is trust, and when it is squandered, something priceless and essential has been lost which may never be recovered. We have considered preventing public panic, exposing the public to unrealistic fear, making a balanced policy, but all of that means nothing if the honesty and integrity of the expert are risked. Honesty, integrity and belief in the competence of the policy makers are core to the ethics of public policy and even the feasibility of public policy. To work well and ethically, policy has to be an interaction of the experts and the public.

Our small window of antibiotic effectiveness is closing and our molecular technology must find other weapons against pathogens; but all our scientific technology can fail if we fail at early detection,

responsible understanding of significance, and rapid response. An E. coli outbreak in Walkerton, Ontario is a good example of how the policy or management side of the defense against pathogens can go terribly wrong. The outbreak killed 6 people and made hundreds ill at the end of May 2000, one of the worst outbreaks of E. coli water contamination in North America. Children became critically ill, and one death was the 2-year-old daughter of a local physician.

In the public perception, E. coli is linked with coliform counts on summer beaches, and sewage contamination. Beach closings because of high counts have become common events in our life, and equally common, the public has often ignored the closings and gone swimming anyway. But there are virulent forms of E. coli, one the emerging E. coli O157:H7. Again, the public is more likely to think of this virulent strain in terms of hamburgers and fast food restaurants than municipal water supplies, or if more informed, of vegetables and cider, or communicable in day care centres. The virulent strain can result in hemolytic uremic syndrome (HUS). A small number of the public may know that this form is a particular risk to children, the elderly, and those with compromised immune systems from cancer treatment, transplants, or HIV.

There is also a question of how well-informed water utilities workers are, though here there is an ethical obligation for them to understand the many potential contaminants and their actual risks. It is no ethical excuse for the chairman of the utility commission in Walkerton to say that workers may not have known how dangerous E. coli O157:H7 can be. They had an ethical obligation based on standards of competence and trust to know. The utility commission was aware of the E. coli contamination before the outbreak occurred according to news reports, but seemed to deny the risk. The manager, said Walkerton's mayor, believed that flushing the system and repairing a chlorinator would solve the problem, another example of a decision made too far toward the extreme point of Don't Panic as opposed to Doomsday. In the end, the workers, used to dealing with standard E. coli counts, had failed the obligation of competence in dealing with emerging virulent strains. The manager, trying to fix problems rather than create them, made a unilateral risk assessment without feedback from other experts

or involvement of the public. The utility system as a whole had not, but ethically should have, recognized the problem[18].

It would be easy to make the utility commission the culprit. There was failure of competence and honesty. In fact, before a local health official issued a boil water order after physicians reported cases of bloody diarrhea, he asked the utility commission three times if the water was free from contamination and was told it was[19]. If that official is correctly reporting, then the commission failed to redeem its first mistake and unethically again denied there was a contamination problem. Honesty and integrity were at high risk, and with their loss, trust would be gone. The Walkerton public is not likely to easily trust public officials and policy makers again, but there are situations where it is crucial that the expert or policy maker be trusted. That is the very harmful result of making policy decisions in an unethical manner, and it is a long-term result that spreads.

However, targeting individuals to blame is not the best ethical analysis, nor can it supply help for future problems. The Exxon Valdez is a case in point. There were problems in the system, and those were the problems that needed attention. Policy functions to identify such systemic problems and make recommendations to avoid them in the future. It is as much learning as regulating. That often means looking at economic factors in the system.

That may not happen in Walkerton. A class-action lawsuit has been filed for the town residents, but the law functions to assign responsibility, decide reparation, and perhaps punish. It is not like policy decisions which look to the future. Three investigations are also underway. Police have interviewed water utility workers and searched documents. Health and environment officials are investigating the cause of the contamination. A coroner's inquest is part of the search. Justice Dennis O'Connor of the Ontario Court of Appeals will hold a public inquiry[20]. Even this will make policy making difficult, because all involved are now in a defensive mode.

On the medical side of the outbreak, the system seemed to have worked well and ethically. Bloody diarrhea was promptly reported to the local health official. One of the pediatricians involved worked closely with the regional medical officer of health to send information

up the system that was vital to good clinical care, such as the contraindication of the use of antibiotics with HUS. The problematic Don't Panic Scenario was not used, and the public was involved honestly.

Why adequate cooperation and openness weren't followed by the local Public Utility Commission needs to be explored, but I don't wish to jump to the conclusion that the commission instituted unethical policy decisions. First, it is likely scientific experts can verify that the outbreak was waterborne, but that needs to be done. Second, the commission's management system may be constructed so that there is a preference for denying problems, in which case, ethical people may act unethically within such a system, no matter the punishment or regulation. Third, economic coercion, economic first-order decisions may have been made by policy makers much higher up the levels of the system than the Walkerton commission. There is even an instance where water safety questions in Quebec were set aside because of NAFTA's global Commission for Environmental Cooperation which is underfunded and under-staffed to take over national policy making from all the countries involved, and has a serious conflict of interest[21]. A full systems analysis is the best ethical methodology here.

The Ethical Mistakes in the Growing West Nile Virus Outbreak and What We Need To Learn From Them

One of the best recent case examples of unethically converting public health policy to public relations and individual burden is West Nile Virus. This flavivirus is related to viruses causing serious or lethal encephalitis around the world (Japanese encephalitis, Murray Valley and St. Louis encephalitis, Stratford virus, e.g.). Until 1999, West Nile virus was unknown in North America. It had been first identified in the West Nile District of Uganda in 1937, so it is not a new emerging virus like Junin or Ebola. In 1957 there was an outbreak in Israel among elderly patients who developed severe meningoencephalitis, and other recent outbreaks include 1994 in Algeria, 1996 in Romania, 1997 in the Czech Republic, and 1999 in Russia. It appears to be a spreading, insect-vectored, bird-hosted virus that has a mortality rate of 3-15%[22].

The first North American outbreak appears to have started in the Queens borough of New York city in 1999, and 62 human cases came

from New York City, Nassau, and Westchester counties, with 7 deaths. A serosurvey of the New York City area affected found 19 of 677 people tested were positive for WNV. With infection rates in healthy dogs at 5-11%, and with confirmed virus in 39% of 758 dead birds tested in New York City and Connecticut[23], spraying with malathion began in New York City. It was promptly criticized by environmentalists. Malathion was applied sparingly and too late in the season, and policy decision makers lost the chance to contain this small outbreak by applying aggressive public health measures. Because the public was reassured that WNV was not transmitted person-to-person or from birds and pets, reassured that the clinical symptoms were generally not life-threatening; and reassured that the risk of becoming infected from one mosquito bite was about 1 in 1000 (far toward the Don't Panic Scenario), there was little support for widespread spraying[24].

The Centers for Disease Control recommended that following active sampling and the detection of WNV, a rapid response of mosquito control be implemented (adulticides, larvicides). The response was neither rapid nor aggressive. The risk assessment made by the public was that spraying chemicals was more dangerous than infection and encephalitis. The opportunity to contain the outbreak vanished over the winter, since Culex mosquitoes winter over without human intervention in ecosystems. A surveillance system/plan was set up with the CDC and the New York State Health Department.

In July 2000, Dr. Antonia Novello, health commissioner, announced that a fast and sensitive DNA PCR test showed WNV in mosquitoes from Westchester and Suffolk counties, the center of the outbreak the previous year. Crows from Staten Island and Rockland county carried WNV, and bring to 19 the WNV-positive birds that year. There were still no human cases. Dr. Novello then contacted the CDC to work on a multi-state, regional plan of action. The policy at this point was that officials were encouraging people to avoid being bitten by mosquitoes, a bit harder now because Aedes japonicus was active from sunrise and Culex from dusk to dawn. The NYS Health Department website listed ways for individuals to reduce breeding sites of mosquitoes to protect themselves. Between drilling holes in recycling containers, cleaning gutters, installing new screens, changing bird baths every

4 days, cleaning pools, clearing vegetation, and landscaping water-collecting areas, the average New York citizen had a full time job. The individual would have to do this job wearing shoes and socks, long pants and long-sleeved shirt, and mosquito repellent containing DEET (except that fully-clothed environmentalists would balk at that last, practical measure because of possible risk). The other suggestion to the individual was that people should stay indoors at dawn, dusk, and early evening[25, 26].

Dead birds continued to be documented, 8 in New York and 1 in New Jersey. A spokesperson for the Health Department said she did not think people needed to be alarmed or avoid outdoor activity, but be aware. There were still no confirmed human cases, but there were hospitalized patients with encephalitis. Neither Suffolk nor Westchester counties had immediate plans to spray, but were beginning to use chemicals to kill mosquito eggs in breeding areas[27]. When 2 dead crows from Staten Island tested positive for WNV, officials planned to spray with Anvil, a natural (and therefore harmless?) pyrethrum from chrysanthemums. Concerns about spraying still outbalanced worry about a new virus, although if this virus had received the public attention and descriptions that Ebola virus did, the balance might have swayed the other way. Too late in the policy game, the New York Times reported the human effects of WNV and its outbreaks in Israel, South Africa and Romania, where hundreds and sometimes thousands of people became ill and the fatality rate was 5-10%. I have still not seen in the public press any statistics for the morbidity rates from WNV in these outbreaks. Beginning ground spraying only in those areas where documented animals cases were found, officials still expected only sporadic cases[28].

By the end of July, a dead crow with WNV was documented in a Syracuse suburb. A county health director gave the response that individuals should be aware and take precautions such as protective clothing and getting rid of stagnant water. By now, the official public policy response was primarily the "Fight-the-Bite" campaign, a series of public relations spots in the media. Surveillance (which was working) and public education (which could accomplish exactly what?) formed the core of the policy. By the end of July, the city of Boston joined the

list with crows testing for WNV and its officials thought about spraying. A 12-year-old child was hospitalized with encephalitis but test results were not public and news stories kept reporting there were no human cases in Massachusetts. The dead birds found 40 miles apart meant the virus had likely penetrated the state. Still, health officials hoped they could get a jump on the virus [29, 30].

In August, a Rochester paper still reported that Western New York had no reported cases in birds, although 5 more counties had confirmed its presence (Albany, Warren, Washington, Dutchess, and Putnam). No confirmed human cases were reported. By now, the NYS Health Commissioner acknowledged that the virus was probably present throughout the state. The policy response was to advise individuals to again reduce stagnant water and protect themselves from being bitten, but no ideas how the typical New Yorker could really accomplish that. Novello didn't feel the news should result in unnecessary alarm (Don't Panic Scenario), and officials said the threat was not enough upstate to recommend a spraying program such as the cities were using. Instead, the public service announcements of "Fight-the-Bite" were running on radio stations statewide[31].

A dead crow with WNV was found in Connecticut, but there were no plans to spray. The state's chief entemologist predicted the virus would spread across the state and New England[32]. By this time, New York City had ruled out 160 possible human cases and was waiting for test results on 40 others. In New Jersey, officials had referred 6 suspect cases to the CDC and were still awaiting results[33].

However, in the first week of August, the New York Times reported that a 78-year-old man from Staten Island had WNV encephalitis. There was no news on the other cases tested, and at least one confirmed case in upstate New York was not being made public. The news reports also suggested that WNV will not pose a major threat in the US. Meanwhile, on the Canadian border, "sentinel chickens" were stationed to sound the first alarm if WNV spread to Canada[34, 35].

By the end of August, our local county health director wanted us to be comfortable thinking WNV was already in our county, because 29 counties in New York, half the state, had documented its presence. The map was getting denser and denser. The health director felt the WNV

problem would get worse if not addressed now, probably true but too late, and the county was considering using larvicides but not spraying. Optimistically, he felt the WNV problem would be with us for the next several years — and of course it will be with us indefinitely, not for just a few years, but endemic. Our county was waiting for test results on 20 dead crows, which could take several weeks, and was not really picking up dead birds but merely noting the number[36]. In fact, despite paper plans for rapid response and surveillance, there was only one laboratory in all of New York State testing dead birds, Ward Stone's Albany lab which was overwhelmed. The policy planners had not increased staffing or facilities for this surveillance plan, nor increased funding. In the real world, the implementation of the policy on paper was not going well. And at the end of August, the New York Times again reported an elderly person, an 87-year-old Brooklyn woman, was critically ill from WNV. The city was planning to spray the Bronx, Brooklyn, and Staten Island[37].

Near the end of September, the understaffed NYS lab began getting results to our county. Dead crows were found in all areas of the country, and a dead hawk was also positive. Dead crows were falling from the sky. One hospital emergency room was doing spinal taps on anyone who came in with a severe headache and fever, and the hospital lab was getting backed up. The county sent a brochure to every mailing address with tips on fighting WNV, including bulldozing property to remove standing water areas[38]. (My son suggested there should be a final paragraph to the brochure, suggesting that if all else had failed, the brochure should be folded and brought down with a swift motion on any flying mosquito.) Israel was reporting a serious outbreak of the same strain of WNV, with 180 sick and 13 deaths so far. Israel also suggested replacing sentinel chickens with geese, since the virus was decimating goose flocks, and geese appeared even more sensitive than chickens as an early warning sign, though in no way a measure of prevention. What can we learn from WNV in North America and the public health policy response?

There is some uncertainty. We do not know what conditions generate the spread, but we do know that the population of North America will have to live with the virus as best it can since it cannot any

longer be contained. We know the spread is both north and south.. We know it is the Israeli strain that is more virulent to birds. We have a top-ten list of possible carriers to New York from Israel (imported poultry, horses and amphibians, hitchhiking mosquitoes, or human travellers whose immune systems are compromised, e.g.)[39]. We don't know if the illness will be a sporadic event or if this virus will amplify as it has in other locations, and this strain has surprised medical experts.

The surveillance plan in the policy was put into effect fairly rapidly, although the public was not always given the most current information and labs were backlogged. Surveillance continued watch, as the virus spread from the first confined outbreak, where containment and elimination might have been possible, to the second year of a state-wide and region-wide spread. Responses to the alert were not adequate. Localized spraying too late in the season lost the chance to prevent the virus from taking hold in the first year. Public health experts tried to find a balance between the risk of WNV and the uncertain risk of pesticide spraying, with the public taking a Doomsday approach to spraying. Because of this ideological rather than scientific factor, officials did not spray as aggressively as needed. Instead of a classic public health response to surveillance data, a decision was made to put most of the burden on the individual through public information/public relations. A public relations campaign was the policy of choice, giving the impression that something substantial was being done. The reality (not the postmodern "conversation") was that there was no measure taken to prevent WNV from becoming endemic in North America. The average citizen has always hoped to avoid being bitten by mosquitoes, and always failed in that hope. The average citizen cannot rearrange the ecosystem so that mosquitoes will not have a place to breed. The policy is ineffective.

Policy focus seemed to be on the Don't Panic Scenario, minimizing the potential risks of a new virus that can cause encephalitis and is virulent to wildlife. The public was given information that was not false in a legal sense, but was deceptively reassuring and made the case for public acceptance that health officials could not prevent a new pathogen from spreading to this continent. Full information was not rapidly given. The reality is that the policy chosen did not support aggressive

health measures soon enough to prevent an insect-vectored disease with 5-10% mortality and unrevealed morbidity from gaining a regional presence.

Major Ethical Concepts of Public Policy in All Three Cases

How and Where on the Don't Panic Scenario vs. Doomsday Scenario to Place the Problem. In addition to factual ambiguity, there is ideological bias in deciding where on this continuum to place the policy issue, as readily seen in the apocalyptic placements of global warming, rain forest destruction, eliminating biodiversity, or assuming scarce resources. The ethical obligation of the expert is to keep within scientific probabilities and reasoned contexts, and create a valid scenario. We know historically, for example, that the public did not panic so badly over the great pneumonic plagues of Eurasia so that civilization came to an end or those in power were slaughered. We know that it is very difficult for any pathogen to completely wipe out a species. False reassurances destroy the trust on which public policy must rely by creating doubt. Crying wolf too many times also creates doubt and dismissal of all risks, even real ones.

Informing and Involving the Public vs. Causing Harm by Premature or Unjustified Precautionary Actions. Often there is a lack of real, substantive public involvement in policy, as expressed in the term for such an expert, "wonk." The BSE example illustrates how a select committee kept information from the public that should have been available, because of concerns about unnecessarily frightening the public at that stage and of doing economic damage to the cattle industry, but neither reason can be ethically justified. A two-tier system of information (common in policy issues) is self-defeating and can be abused to protect the policy maker, not the public. Pseudoinvolvement in policy is also a strategy sometimes used by policy makers, with the form and trappings of an interaction, but no true interaction. While there may be some situations where the harm is severe enough to justify not informing and involving, my argument would be that these situations are rare except in national emergencies such as wartime, and even there must be used sparingly or be self-defeating. Informing and

involving the public is a preferred balance to the power of experts and the strategems of public relations.

Expert Standards of Objective, Rational Thinking/Expect Obligation. An expert ought to be aware of conflict and bias, correct to the best of his or her ability, and identify those conflicts so that others may help in the correction. An expert needs to be open to new experiences or data and not prematurely come to a consensus or defend a questionable consensus, as many AIDS/HIV experts did. An expert should be honest with public information, not simply in terms of direct lies, but more importantly in terms of deliberate, subtle deceptions. An expert should avoid public relations techniques which are manipulative and do not create ethical public policy, such as the "Fight-the-Bite" campaign which would make a sentient mosquito laugh hysterically. An expert has the obligation to be adequately competent, one that the water utility workers may have failed. Finally, experts will disagree, which is not a bad thing given the openness of science.

Risk Assessment and Risk/Benefit Analysis. Trade-offs are part of the natural system. An ethical assessment needs to be as verified as required, but not absolutely proved. Risk assessment needs to be broken down into its 3 components and those components relayed to the public so they can have an understanding of their own responses that will help. Although we can conflate risk with economic cost, we can look at a person's willingness to pay a certain price as a marker, in the end risk/benefit analysis is an ethical judgment made within an ethical theory, not a political or economic science, or even a statistical trade-off theory.

Uncertainty in Ethics. Policy planning contains an uncertainty factor that may be small or substantial, as seen in BSE or WNV. As with clinicians, uncertainty is not an excuse for negligence, incompetence, malevolence or deception and manipulation. Remaining open to feedback rather than becoming over-committed to protocols, hearing the ping of experiences that do not fit the carefully-constructed but still only approximate analysis and plan, is both an ethical and scientific

requirement. As William James put it, one needs to hear the cries of the wounded, those wounded by evaluations, plans, strategies, and judgments[40].

Balance in a System. The core ethical concept that makes systems bioethics a useful tool for policy as well as ethics is the concept of a balance point within the levels of a natural system. Public Policy is basically the discipline of finding the optimum balance point, the flexible integration of as many functions at all levels as is realistic. Balance is not a steady-state but a controlled-state oscillation. Preference can be ethically given to critical malfunction solutions at one level, but only if feedback from other levels is considered and acceptable. Only in extreme cases would extreme ethical choices be made that sacrificed major needs of any one level. The ethical choice is not automatically the middle, but a balance that may shift as situations shift, that may sometimes require the extreme sacrifice, that often requires the ongoing compensation for multiple reactions at multiple levels. None of this can be governed by ideology, however, which cannot hope to supply the dynamic concepts that systems theory requires.

The Underlying Politicizing Caused by Postmodern Bioethics and Some Help From Systems Theory and the Re-Enlightenment

There is no space to develop my contention that postmodern bioethics is irrational and unworkable and needs to be replaced by a nonpoliticized bioethics such as systems bioethics. I would refer you to the book I have just completed which makes that argument in detail. Every institution which is politicized is one step closer to the total society and the loss of world knowledge, as well as a block to doing ethical public policy.

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Notes on Contributors / Notices biographiques des conférenciers

Colleen Clements, a National Science Foundation Fellow and previous Coordinator of an NIMH AIDS Training Grant, is an adjunct clinical associate professor of psychiatry at the University of Rochester School of Medicine, where she is on the faculty of the Psychiatry Department's Forensic Psychiatry Fellowship. She is also a monthly ethics columnist for The Medical Post, a contributor to the Ross Foundation, and an expert witness in malpractice and sexual abuse cases. Dr. Clements is the author of *Medical Genetics Casebook*; *Science and Morality*; *AIDS, Health and Mental Health*; and the upcoming *Postmodern Malpractice*. Her work on medical ethics, forensic ethics and environmental ethics has been anthologized, and original chapters appear on issues in medical education, law, end of life decisions, and critiques of postmodern medical ethics. Articles in professional journals include the Journal of the American Psychiatric Association, Annals of Psychiatry, JAMA, Ethics, Philosophy and Phenomenological Research, British Journal of Medical Ethics, Chest, and Perspective in Biology and Medicine.

Colleen Clements, membre de la National Science Foundation et ancienne coordonnatrice d'une subvention à la formation de l'agence NIMH AIDS, est professeure adjointe en psychiatrie clinique à la Faculté de médecine de l'University of Rochester où elle fait partie du corps professoral de la dotation de psychiatrie médico-légale du Département de psychiatrie. Elle publie également une chronique mensuelle de déontologie dans The Medical Post, elle collabore à la Fondation Ross et est souvent citée en qualité de témoin expert dans des causes de négligence professionnelle et d'agression sexuelle. La prof. Clements est l'auteure de *Medical Genetics Casebook: Science and Morality* et de *AIDS, Health and Mental Health*, ainsi que d'un ouvrage a paraître sous le titre *Postmodern Malpractice*. Ses travaux sur la déontologie médicale, l'éthique médico-légale et l'éthique environnementale sont cités dans les anthologies, et notamment plusieurs chapitres originaux

sur l'enseignement de la médecine, le droit, l'acharnement thérapeutique et la critique de la déontologie médicale postmoderne. Elle a publié des articles dans des revues professionnelles et savantes comme le Journal of the American Psychiatric Association, Annals of Psychiatry, JAMA, Ethics, Philosophy and Phenomenological Research, le British Journal of Medical Ethics, Chest, et Perspective in Biology and Medicine.

Bernard M. Dickens, FRSC, LL.B. 1961, LL.M. 1965, Ph.D. (Law-Criminology) 1971, LL.D. (Medical Jurisprudence) 1978 (London), called to the English Bar in 1963 and the Ontario Bar in 1977, is a Professor in the Faculty of Law, the Faculty of Medicine, and the Joint Centre for Bioethics at the University of Toronto. Professor Dickens specializes in law and medicine, and is legal articles editor of the *Journal of Law, Medicine and Ethics* and serves as a member of the editorial boards of several journals including the *American Journal of Law and Medicine* and *Medicine and the Law*. He has been a consultant on several projects of the World Health Organization, including on issues in organ transplantation and research involving human subjects. His writing includes over three hundred publications including books, chapters in books, articles and reports primarily in the field of medical and health law, including Bioethics in Canada (1993, with D. Roy and J. Williams). He was President of the American Society of Law, Medicine and Ethics in 1990-91. From 1994 he has been on the Board of Governors of the World Association for Medical Law, and has been a Vice President since 1996. From 1995 to 1999 he was Chairman of the Human Subjects Research Ethics Committee of the National Research Council of Canada, in Ottawa.

Bernard M. Dickens, FRSC, LL.B. (1961), LL.M. (1965), Ph.D. en droit et criminologie (1971), LL.D. en jurisprudence médicale (1978, Londres), a été appelé au Barreau anglais en 1963 et à celui de l'Ontario en 1977. Il est professeur à la Faculté de droit, à la Faculté de médecine et au Joint Centre for Bioethics de l'University of Toronto. Le prof. Dickens est un spécialiste du droit et de la médecine et il dirige la publication des articles à caractère juridique du *Journal of Law, Medicine and Ethics*. Il siège au comité de rédaction de plusieurs revues dont

l'*American Journal of Law and Medicine* et *Medicine and the Law*. Il a fait fonction de consultant dans le cadre de plusieurs projets de l'Organisation mondiale de la santé, notamment au sujet de questions de transplantation d'organes et de recherche sur des sujets humains. Il a signé plus de trois cents publications dont des livres, des chapitres d'ouvrages, des articles et des rapports consacrés principalement au droit médico-sanitaire comme *Bioethics in Canada* (1993, en collaboration avec D. Roy et J. Williams). Il a été, de 1990 à 1991, le président de l'American Society of Law, Medicine and Ethics. Il fait partie depuis 1994 du conseil d'administration de l'Association mondiale pour le droit médical dont il occupe la vice-présidence depuis 1996. De 1995 à 1999, il a été le président du Comité de déontologie pour la recherche sur des sujets humains du Conseil national de recherches du Canada à Ottawa.

Michael Geist is a law professor at the University of Ottawa specializing in Internet and e-commerce law. Professor Geist has obtained law degrees from Osgoode Hall Law School in Toronto, Cambridge University in the UK, and Columbia Law School in New York. He has written numerous academic articles and government reports on the Internet and law, is national columnist on cyberlaw issues for the Globe and Mail, the author of Internet Law in Canada (Captus), editor of the monthly newsletter, Internet and E-commerce Law in Canada (Butterworths), the creator and founder of BNA's Internet Law News, and on the advisory boards of several leading Internet law publications including Electronic Commerce & Law Report (BNA), the Journal of Internet Law (Aspen) and Internet Law and Business (Computer Law Reporter). He is regularly quoted in the national and international media on Internet law issues and has appeared before government committees on e-commerce policy.

Michael Geist, professeur à l'Université d'Ottawa, a pour spécialisation le droit relatif à l'Internet et au commerce électronique. Il est diplômé en droit d'Osgoode Hall à Toronto, de l'Université de Cambridge au Royaume-Uni et de la Faculté de droit de l'Université Columbia à New York. Il a écrit de nombreux articles savants et rapports officiels concernant l'Internet et le droit et il signe une chronique sur le cyberdroit dans l'édition nationale du Globe and Mail; auteur

de Internet Law In Canada (Captus), il est également le rédacteur en chef du bulletin mensuel *Internet and E-commerce Law in Canada* (Butterworth) et le créateur-fondateur d'*Internet Law News* (BNA); il siège par ailleurs au conseil de rédaction de plusieurs publications de renom consacrées au droit et à l'Internet dont *Electronic Commerce & Law Report* (BNA), le *Journal of Internet Law* (Aspen) et *Internet Law and Business* (Computer Law Reporter). Il est souvent cité dans sa spécialité par les médias canadiens et étrangers et a témoigné devant des comités officiels au sujet de la politique en matière de commerce électronique.

Thérèse Leroux a un doctorat en biochimie médicale de l'Université Laval (1981) et une licence en droit de l'Université de Sherbrooke (1984). Depuis 1987, elle est membre du Centre de recherche en droit public de l'Université de Montréal. Elle a été la présidente de la Société canadienne de bioéthique/The Canadian Bioethics Society en 1998-1999. La prof. Leroux a codirigé la publication de l'ouvrage *L'être humain, l'animal et l'environment : dimensions éthiques et juridiques* (1996) et a signé de nombreux articles dont "An overview of public consultation mecanisms developed abroad to address the ethical and social issues raised by biotechnology" (1998). Les travaux de recherche qu'elle conduit actuellement sont axés notamment sur des projets relatifs aux problématiques éthiques et juridiques posées par les animaux transgéniques et la xénotransplantation, ainsi que sur l'efficacité des lois sur la protection de l'environnement en matière de réglementation de la biotechnologie.

Thérèse Leroux received a doctorate in medical biochemistry from Université Laval in 1981 and a law degree from Université de Sherbrooke in 1984, and since 1987 has been a member of the Centre de recherche en droit public at Université de Montréal. She was President of La Société canadienne de bioéthique/The Canadian Bioethics Society in 1998-9. Dr. Leroux co-edited the volume (in French), *Humans, Animals and the Environment: Ethical and Legal Dimensions* (1996) and is the author of numerous articles, including "An overview of public consultation mechanisms developed abroad to address the ethical and social issues raised by biotechnology" (1998). Her current

research includes projects on ethical and legal issues raised by transgenic animals and xenotransplantation and the adequacy of environmental protection legislation for the regulation of biotechnology.

Michael McDonald is the first occupant of the Maurice Young Chair of Applied Ethics and founding director of the Centre for Applied Ethics, The University of British Columbia. His research interests are in health care ethics, business and professional ethics, political philosophy, and philosophy of law. Most recently he was the Principal Investigator for a study of the "Governance of Health Research Involving Human Subjects" for the Law Commission of Canada. McDonald is the Past-President of the Canadian Philosophical Association and former Editor of its journal, *Dialogue*. Before coming to UBC in 1990, he served as a member of the Philosophy Department at the University of Waterloo for twenty-one years.

Michael McDonald a été le premier à occuper la chaire d'éthique appliquée Maurice Young, et il fut le directeur-fondateur du Centre for Applied Ethics de l'University of British Columbia. Il axe ses travaux de recherche sur la déontologie dans le domaine des soins de santé, l'éthique professionnelle et commerciale, la philosophie politique et la philosophie du droit. Il a été tout récemment l'enquêteur principal lors de la conduite d'une étude sur "La gouvernance des recherches médico-sanitaires faisant intervenir des sujets humains" pour le compte de la Commission canadienne du droit. Le prof. McDonald est le président sortant de l'Association canadienne de philosophie et il a également été le rédacteur en chef de *Dialogue*, sa revue officielle. Avant de commencer àenseigner à l'University of British Columbia en 1990, il a fait partie pendant 21 ans du corps professoral du Département de philosophie de l'University of Waterloo.

Marie-Hélène Parizeau est professeur titulaire à la faculté de philosophie de l'Université Laval. Elle enseigne l'éthique médicale en faculté de médecine et l'éthique de l'environnement au département de microbiologie. Madame Parizeau est membre de comités d'éthique appliquée et a dirigé plusieurs ouvrages collectifs : *Fondements de la bioéthique* (De Boeck, 1991) ; *Les mots de la bioéthique* (en

collaboration avec G. Hottois, De Boeck, 1993) ; *L'hôpital et éthique* (Presses de l'Université Laval, 1995), *La biodiversité* (De Boeck, 1997)

Marie-Hélène Parizeau is full professor in the Department of Philosophy at the Université Laval. She lectures in medical ethics in the School of Medicine, and in environmental ethics in the Department of Microbiology. Professor Parizeau serves as member in various applied ethics committees and has edited several collective publications including *Fondements de la bioéthique* (De Boeck, 1991), *Les mots de la bioéthique* (with G. Hottois, De Boeck, 1993), *L'hôpital et l'éthique* (Presses de l'Université Laval, 1995), et *La biodiversité* (De Boeck, 1997)